October 31, 2024

highness Co., Ltd.
℅ Sanghwa Myung
Regulatory Affair Specialist
E&m
D1474, PyeongCheon Arco Tower, 230, Simin-Daro, Dongan-gu
Anyangsi, Gyeonggido 14067
KOREA, SOUTH

Re: K240383
Trade/Device Name: Highness Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: February 8, 2024
Received: October 3, 2024

Dear Sanghwa Myung:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT0 OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Indications for Use

510(k) Number *(if known)*

K240383

Device Name

Highness Implant System

Indications for Use *(Describe)*

The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading.
The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
For
Highness Implant System

[Complying with 21 CFR 807.92]

I. SUBMISSION SPONSOR

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Contact Person: Ms. Ji-yun Jeong, RA Manager

II. SUBMISSION CORRESPONDENT

E&M
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Anyangsi, 14067, Republic of Korea
Cell Phone: +82-10-4952-6638
Office Phone: +82-70-7807-0550
Contact: Ms. Sang-hwa Myung, Regulatory Affair Specialist
Email: mshenmc@gmail.com

III. DATE PREPARED

October 31, 2024

IV. DEVICE

Trade or Proprietary Name:	Highness Implant System
Common or Usual Name:	Endosseous Dental Implant
Classification Name:	Endosseous dental implant (21 CFR 872.3640)
Regulatory Class:	II
Product Code:	DZE, NHA
Classification Panel:	Dental

V. PRIMARY PREDICATE AND REFERENCE DEVICES

Primary Predicate Device:
K182448, AnyRidge Octa 1 Implant System/ MegaGen Implant Co., Ltd.

Reference Devices:

K123988, AnyOne ™ Internal Implant System / MegaGen Implant Co., Ltd.

K192347, Solid Abutment for ST Internal Implant System / Megagen Implant Co. Ltd.

K203808, Multi-unit Abutment For Multi-unit Abutment, Multi-unit Angled Abutment / Megagen Implant Co. Ltd.

K110955, Healing Abutment for AnyRidge Internal System / Megagen Implant Co. Ltd.

K160519, Link Abutment for CEREC / OSSTEM Implant Co., Ltd.

VI. DEVICE DESCRIPTION

The Highness Implant System is a titanium-metal dental implant designed to be surgically placed in the bone of the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

The Highness Implant System consists of fixtures and abutments.

The fixture is made of pure titanium metal and is supplied sterile (gamma irradiated). The surface is SLA, sandblasted (using 425-180-micron MCD apatitic abrasive, which is a granular, multi-phase calcium phosphate composed primarily of hydroxyapatite and tricalcium phosphate), large grit, acid-etched (solution of hydrochloric acid and nitric acid), treated.

The dimensional range of the fixture is as follows:

Fixture	Diameter (ø)	Length (mm)
HS-I	4.2, 4.6, 5.1, 5.6, 6.0, 7.0	7.0, 8.5, 10, 11.5, 13, 14.5
HS-VII	4.2, 4.7, 5.2, 5.7, 6.2, 7.0	7.0, 8.5, 10, 11.5, 13, 14.5

The abutments are made of Ti-6Al-4V ELI titanium alloy (ASTM F136). It consists of a Cemented Abutment, Angled Abutment, Solid Abutment, Temporary Abutment, and Multi-Unit Abutment Screw & Abutment Screw, which are intended for use as an aid in single- or multiple-unit prosthetic restorations, and the Multi-Unit Abutment and Multi-Angled Abutment, which are intended for use only as aids in multiple-unit prosthetic restorations. In addition, Cover Screws and Healing Abutments are prefabricated prosthetic components that connect directly to endosseous dental implants and are indicated as temporary components to allow for soft tissue healing. All abutments are supplied non-sterile and individually packaged in FDA cleared wraps and/or pouches. The abutments should be sterilized prior to use by the end-user. And temporary abutments are intended to be used 6 months.

The abutments are compatible with both HS - I and HS - VII implant bodies.

The abutment's dimension range is as follows:

Abutment	Diameter (ø)	Post Height (mm)	Cuff Height (mm)	Angulation (°)	Surface
Cemented Abutment	4.5, 5.0, 5.5, 6.0, 6.5	4.0, 5.5, 7.0	0.5, 1.0, 2.0, 3.0, 4.0, 5.0	-	Machined
Angled Abutment	4.5, 5.0, 5.5	8.0	1.0, 2.0, 3.0,	15, 17, 25	Machined

Abutment	Diameter (ø)	Post Height (mm)	Cuff Height (mm)	Angulation (°)	Surface
			4.0, 5.0		
Solid Abutment	4.0, 4.5, 5.0, 5.5, 6.0, 6.5	4.0, 5.5, 7.0	1.0, 2.0, 3.0, 4.0, 5.0	-	Machined
Multi-Unit Abutment	4.8	2.3	1.0, 2.0, 3.0, 4.0, 5.0	Straight	Machined
Multi-Unit Angled Abutment	4.5	2.3	2.0, 3.0, 4.0, 5.0	15, 17, 25	Machined
Temporary Abutment	4.0, 4.5, 5.0, 5.5, 6.0, 6.5	9.75, 10.75, 11.75	1.0, 2.0, 3.0	-	Machined
Healing Abutment	4.2, ,4.7, 5.2, 5.7, 6.2, 6.7	-	3.0, 4.0, 5.0, 6.0, 7.0	-	Machined
Abutment Screw, Multi-Unit Abutment Screw	2.05, 2.3	7.5, 9.5	-	-	Machined
Cover Screw	3.6	5.4	-	-	Machined

VII. INDICATION FOR USE

The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading.

The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

<Substantial Equivalence to Predicate Devices Table – Fixture>

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**REFERENCE Device (K123988)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGenImplant Co., Ltd.**	–
Trade Name	Highness Implant System	AnyRidge Octa 1 Implant System	AnyOne ™ Internal Implant System	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Identical
Regulation Number	21 CFR 872.3640	21 CFR 872.3640	21 CFR 872.3640	Identical
Product Code	DZE	DZE	DZE	Identical
Class	II	II	II	Identical
Indications for Use	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: - Delayed loading. - Immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The AnyOne ™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 06.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are	similar

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K123988)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGenImplant Co., Ltd.**	–
	and are indicated for delayed loading. The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.	Larger implants are dedicated for the molar region.	indicated for delayed loading.	
Implant design	Root-form endosseous dental implants 	Root-form endosseous dental implants 	Root-form endosseous dental implants 	Similar
Anti-Rotational Feature	Internal Hex	Internal Octa	Internal Hex	Similar
Diameter (ø)	HS-I: 4.2, 4.6, 5.1, 5.6, 6.0, 7.0 mm HS-VII: 4.2, 4.7, 5.2, 5.7, 6.2, 7.0 mm	3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5 mm	3.9, 4.3, 4.8, 5.3, 6.3, 7.3 mm (for normal thread); 4.8, 5.8, 6.8, 7.8, 8.3 mm (for deep thread); and 4.8, 5.3, 6.3, 7.3 mm (for special length)	Similar
Length (mm)	7.0, 8.5, 10, 11.5, 13, 14.5(not available for the 7.0mm diameter) mm	7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm	7.0, 8.0, 9.5, 11.0, 12.5, 14.5 mm (for normal and deep thread); 7.0 mm (for special length)	Similar
Raw material	CP Titanium Grade 4	CP Titanium Grade 4	CP Titanium Grade 4 and Ti-6A1-4V-ELI Titanium Alloy	Identical
Surface Treatment	SLA	SLA	SLA	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K123988)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGenImplant Co., Ltd.**	–
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization	Identical
Single Use	Yes	Yes	Yes	Identical
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Identical
Principle of Operation	This product is a root-type fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	Identical
Shelf-life	5 years	5 years	-	Identical
SE	Information provided in these 510(k) submissions shows that the Highness Implant System is substantially equivalent to the primary predicate device, in terms of indications for use, principle of operation, surface treatment, sterilization method, function and performance related to technological characteristics. Differences between the proposed and primary predicate device are not expected to affect the overall performance of the device. There are slightly different diameter and length between the subject and primary predicate device. The implant length range of the subject device is within the range of the predicate devices. However, there is an additions diameter in the subject device comparing to the predicate device. The difference in length is minor, but the AnyOne ™ Internal Implant System was used by MegaGenImplant Co., Ltd. to support these lengths. And the reference device is made of the same material as the subject device, CP Ti Grade 4 same as our device material; it is not introducing significantly different design, and the performance test results supported that this difference does not raise an issue in performance.			

<Substantial Equivalence to Predicate Devices Table – Abutment>

1) Cemented Abutment

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K160519)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**OSSTEM Implant Co., Ltd**	–
Trade Name	Cemented Abutment for	EZ Post Abutment for AnyRidge	Link Abutment for CEREC	–

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**REFERENCE Device (K160519)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**OSSTEM Implant Co., Ltd**	–
	Highness Implant System	Octa 1 System		
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	NHA	Identical
Class	II	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading. The Multi-Unit Abutments are	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading, -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The Link Abutment for CEREC is titanium alloy abutments placed onto HIOSSEN dental implants to provide support for customized prosthetic restorations. Link Abutment for CEREC is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. - Link abutment for CEREC All digitally designed copings and/or crowns for use with the Link abutment for CEREC is to be scanned using Sirona CEREC AC or CEREC AF or CEREC AI, designed using Sirona inLab software (Version 3.65) or Sirona CEREC Software (Version 4.2) and manufactured using a	Similar: Indications for use of the subject device is slightly different from the primary predicate in phrase but fundamental indication from the reference devices is the identical.

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K160519)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**OSSTEM Implant Co., Ltd**	–
	intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.		Sirona CEREC or inLab MC X or MC XL milling unit. CAD/CAM manufacturing/milling occurs at dental laboratories per the design limitations of the Sirona CEREC.	
Design				Similar
Diameter (ø)	4.5, 5.0, 5.5, 6.0, 6.5 mm	4.0, 5.0, 6.0, 7.0 mm	4.5 mm	Similar
Post Height	4.0, 5.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm	4.7 mm	Identical
Cuff Height	0.5, 1.0, 2.0, 3.0, 4.0, 5.0 mm	0.8, 1.8, 2.8, 3.8, 4.8 mm	0.5 mm	Similar
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Hex, Non-hex	Octa, Non-octa	Hex, Non-hex	Similar
Surface Treatment	Non-Anodizing	Anodizing		Identical
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Identical
Single Use	Yes	Yes	Yes	Identical
Restoration type	Single & Multi	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1–	Identical
Principle of Operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K160519)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**OSSTEM Implant Co., Ltd**	–
	of the missing teeth as a dental abutment.	of the missing teeth as a dental abutment.	of the missing teeth as a dental abutment.	
SE	The subject device has the same intended use, material, principle of operation and similar design as the predicate device and re, and there are slightly different dimensions. However, the abutment diameter and angulation range of the subject device is within the range of the predicate device. And the subject device has slightly different of post height and Cuff Height. However, this post height and gingival range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. Also, the connection interface is different but both features of Octa and Hex provides anti-rotational feature. Therefore, it is substantial equivalent.			

2) Angled Abutment

	SUBJECT Device	Primary PREDICATE Device (K182448)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Trade Name	Angled Abutment for Highness Implant System	Angled Abutment for AnyRidge Octa 1 System	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	Identical
Class	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols:	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading. The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.	-Delayed loading, -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	
Design			Similar
Diameter (ø)	4.5, 5.0, 5.5 mm	4.0, 5.0, 6.0, 7.0 mm	Similar
Post Height	8.0 mm	7.0 mm	Similar
Cuff Height	1.0, 2.0, 3.0, 4.0, 5.0 mm	0.8, 1.8, 2.8, 3.8, 4.8 mm	Similar
Angulation	15°, 17°, 25°	15°, 25°	Similar
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Hex, Non-hex	Octa, Non-octa	Similar
Surface Treatment	Non-Anodizing	Anodizing	Identical
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Identical
Single Use	Yes	Yes	Identical
Restoration type	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Identical
Principle of Operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
		dental abutment.	
SE	The subject device has the same intended use, material, principle of operation and similar design as the predicate device, and there are slightly different dimensions. However, the abutment diameter and angulation range of the subject device is within the range of the predicate device. And the subject device has slightly different of post height and Cuff Height. However, this post height and gingival range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. Also, the connection interface is different but both features of Octa and Hex provides anti-rotational feature. Therefore, it is substantial equivalent.		

3) Solid Abutment

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K192347)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**Megagen Implant Co. Ltd.**	–
Trade Name	Solid Abutment for Highness Implant System	Octa Abutment For AnyRidge Octa 1 System	Solid Abutment for ST Internal Implant System	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	NHA	Identical
Class	II	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K192347)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**Megagen Implant Co. Ltd.**	–
	patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading. The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.	chewing function in the following situations and with the clinical protocols: -Delayed loading, -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	
Design				Similar
Diameter (ø)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5 mm	3.8 mm	4.0, 4.6, 5.0, 6.0, 7.0 mm	Similar
Post Height	4.0, 5.5, 7.0 mm	Unknown	4.0, 5.5, 7.0 mm	Similar
Cuff Height	1.0, 2.0, 3.0, 4.0, 5.0 mm	0.8, 1.8, 2.8, 3.8, 4.8 mm	1.0, 2.0, 3.0, 4.0, 5.0 mm	Similar
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Hex	Internal Conical connection	Hex	Similar
Surface Treatment	Non-Anodizing	Color anodization	Anodizing	Similar
Sterilization	Non-sterile; Steam sterilization	Non-sterile; Steam sterilization	Non-Sterile (user sterilization),	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K192347)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**Megagen Implant Co. Ltd.**	–
	prior to use	prior to use	or sterile (Radiation)	
Single Use	Yes	Yes	Yes	Identical
Restoration type	Single & Multi	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Identical
Principle of Operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	Identical
SE	The subject device has the same intended use, material, principle of operation and similar design as the primary predicate, and there are different dimensions. However, the abutment diameter, post height and Cuff Height range of the subject device is within the range of the reference device. These differences do not affect product's fundamental function. Also, the connection interface is different but both features of Octa and Hex provides anti-rotational feature. Therefore, it is substantial equivalent.			

4) Multi-Unit Abutment

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K203808)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Trade Name	Multi Angled Abutment for Highness Implant System	Multi-unit Abutment For Multi-unit Abutment, Multi-unit Angled Abutment	Multi-unit Abutment For Multi-unit Abutment, Multi-unit Angled Abutment	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	NHA	Identical

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**REFERENCE Device (K203808)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Class	II	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading. The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K203808)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Design				Similar
Diameter (ø)	4.8 mm	4.8, 5.0 mm	4.8, 5.0 mm	Identical
Post Height	2.3 mm	1.8, 2.2 mm	1.8, 2.2 mm	Similar
Cuff Height	1.0, 2.0, 3.0, 4.0, 5.0 mm	0.6, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm	0.6, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm	Similar
Angulation	Straight	Straight	Straight	Identical
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Hex	Octa, Non-octa	Internal Hex, Internal Non-Hex, Internal Conical Connection	Similar
Surface Treatment	Non-Anodizing	Color Anodization	Anodizing	Similar
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Identical
Single Use	Yes	Yes	Yes	Identical
Restoration type	Multi	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Identical
Principle of Operation	This product is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	Multi-unit Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.	Identical
SE	The subject device has the same intended use, material, principle of operation and similar design as the predicate device, and there is slightly different Cuff Height. However, the Cuff Height range of the subject device is within the range of the reference device. And the subject device has slightly different of post height. However, this post height range is to meet each patient needs and does not raise an			

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K203808)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	issue in performance or safety since the size difference is very minor. Also, the connection interface is different but both features of Octa and Hex provides anti-rotational feature. Therefore, it is substantial equivalent.			

5) Multi-Unit Angled Abutment

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K203808)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Trade Name	Multi Angled Abutment for Highness Implant System	Multi-unit Angled Abutment for AnyRidge Octa 1 System	Multi-unit Angled Abutment For Multi-unit Abutment, Multi-unit Angled Abutment	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	NHA	Identical
Class	II	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K203808)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading. The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.	following situations and with the clinical protocols: -Delayed loading, -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.		
Design				Similar
Diameter (ø)	4.5 mm	4.8 mm	4.8, 5.0 mm	Identical
Cuff Height	2.0, 3.0, 4.0, 5.0 mm	2.3, 3.3, 4.3 mm	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 mm	Similar
Angulation	15°, 17°, 25°	17°, 30°	17°, 29°, 30°	Similar
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Hex	Octa, Non-octa	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa	Similar
Surface Treatment	Non-Anodizing	Non-Anodizing	Anodizing	Identical
Sterilization	Non-sterile; Steam sterilization	Non-sterile; Steam sterilization	Non-Sterile (user sterilization),	Identical

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**REFERENCE Device (K203808)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	prior to use	prior to use	or sterile (Radiation)	
Single Use	Yes	Yes	Yes	Identical
Restoration type	Multi	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Identical
Principle of Operation	Multi-unit Angled Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	Multi-unit Angled Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.	Identical
SE	The subject device has the same intended use, material, principle of operation and similar design as the primary predicate, and there are different dimensions. However, the abutment diameter, Cuff Height and angulation range of the subject device is within the range of the reference device. These differences do not affect product's fundamental function. Also, the connection interface is different but both features of Octa and Hex provides anti-rotational feature. Therefore, it is substantial equivalent.			

6) Multi-unit Abutment Screw & Abutment Screw

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**REFERENCE Device (K203808)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Trade Name	Abutment Screw, Multi-unit Abutment Screw for Highness Implant System	Multi-unit Abutment Screw For AnyRidge Octa 1 Implant System	Multi Angled Abutment Screw	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	NHA	Identical

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**REFERENCE Device (K203808)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Class	II	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading. The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading, -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K203808)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Design				Similar
Diameter (ø)	2.05 mm; 2.3 mm	2.1, 2.2 mm	2.1, 2.2, 2.4, 2.95 mm	Similar
Total Length	7.5 mm; 9.5 mm	7.0, 7.9 mm	4.4, 6.8, 7.0, 10.8, 11.5, 11.8, 12.5, 12.8, 13.5, 13.8, 14.5, 15.5 mm	Similar
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Identical
Surface Treatment	Machined	Machined	Machined, Anodizing	Identical
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Non-Sterile (user sterilization), or sterile (Radiation)	Identical
Single Use	Yes	Yes	Yes	Identical
Restoration type	Single & Multi	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	–	Identical
Principle of Operation	Abutment Screw and Multi-unit Abutment Screw is used for connecting Abutment or Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.	Multi-unit Abutment Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.	Multi-unit Abutment Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.	Identical
SE	The subject device has the same intended use, material, principle of operation and similar design as the primary predicate, and there are different dimensions. However, the abutment diameter, Cuff Height and angulation range of the subject device is within the range of the reference device. These differences do not affect product's fundamental function. Also, the connection interface is different but			

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K203808)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	both features of Octa and Hex provides anti-rotational feature. Therefore, it is substantial equivalent.			

7) Temporary Abutment

	SUBJECT Device	Primary PREDICATE Device (K182448)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Trade Name	Temporary Abutment for Highness Implant System	Temporary Abutment for AnyRidge Octa 1 System	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	–
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	Identical
Class	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading. The Multi-Unit Abutments are intended for multi-unit restorations only and can be used	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading, -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	up to 25 degrees when connecting cylinder.		
Design			Similar
Diameter (ø)	4.0, 4.5, 5.0, 5.5, 6.0, 6.5 mm	4.0, 5.0 mm	Similar
Post Height	9.75, 10.75, 11.75 mm	10 mm	Similar
Cuff Height	1.0, 2.0, 3.0 mm	2.0, 3.0 mm	Similar
Angulation	0°	0°	Identical
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Hex, Non-Hex	Octa, Non-octa	Similar
Surface Treatment	Non-Anodizing	Color Anodization	Similar
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Identical
Single Use	Yes	Yes	Identical
Restoration type	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Identical
Principle of Operation	Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration.	Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration.	Identical
SE	The subject device has the same intended use, material, principle of operation and similar design as the predicate device. However, there are different dimensions. The subject device has slightly wider range of diameter, post height and Cuff Height. This wider range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor; therefore, it is substantial equivalent. Also, the connection interface is also different but both features of Octa and Hex provides anti-rotational feature.		

8) Healing Abutment

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**REFERENCE Device (K110955)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Trade Name	Healing Abutment for Highness Implant System	Healing Abutment for AnyRidge Octa 1 System	Healing Abutment for AnyRidge Internal System	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	Endosseous Dental Implant System	Identical
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	NHA	Identical
Class	II	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the molar region and are indicated for delayed loading.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading, -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	Identical

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**REFERENCE Device (K110955)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.			
Design				Similar
Diameter (ø)	4.2, ,4.7, 5.2, 5.7, 6.2, 6.7 mm	3.2, 4.2, 5.2, 6.2 mm	4.2, 5.2, 6.2, 7.2, 8.0, 10.0 mm	Similar
Cuff Height	3.0, 4.0, 5.0, 6.0, 7.0 mm	2.5, 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5 mm	3.5, 4.5, 5.5, 6.5, 7.5 mm	Similar
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Identical
Surface Treatment	Machined	Color Anodization	Machined	Similar
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Non-Sterile (user sterilization), or sterile (Radiation)	Identical
Single Use	Yes	Yes	Yes	Identical
Restoration type	Single & Multi	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Biocompatible in accordance with ISO 10993-1	Identical
Principle of Operation	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.	Identical
SE	The subject device has the same intended use, principle of operation, material, connection interface, and similar design as the predicate devices, and there are slightly different diameter and cuff height. However, the diameter and cuff height range of the subject device is			

	SUBJECT Device	Primary PREDICATE Device (K182448)	REFERENCE Device (K110955)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	within the range of the predicate devices. However, this diameter and cuff height range is to meet each patient needs and does not raise an issue in performance or safety since the size difference is very minor. The other difference is in surface treatment, but we already presented multiple predicate devices for anodizing in the other component comparison charts. Therefore, it is substantial equivalent.			

9) Cover Screw

	SUBJECT Device	Primary PREDICATE Device (K182448)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
Trade Name	Cover Screw for Highness Implant System	Cover Screw For AnyRidge Octa 1 Implant System	–
Regulation Description	Endosseous Dental Implant System	Endosseous Dental Implant System	–
Regulation Number	21 CFR 872.3630	21 CFR 872.3630	Identical
Product Code	NHA	NHA	Identical
Class	II	II	Identical
Indications	The Highness Implant System is designed to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (crowns, bridges, and overdentures) in partially or fully edentulous individuals. It is used to the restore the patient's chewing function. Implants with diameter less than ø5.5mm are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated to the	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading, -Immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Identical

	SUBJECT Device	Primary PREDICATE Device (K182448)	Significant Difference
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	molar region and are indicated for delayed loading. The Multi-Unit Abutments are intended for multi-unit restorations only and can be used up to 25 degrees when connecting cylinder.	Larger implants are dedicated for the molar region.	
Design			Similar
Diameter (ø)	3.6 mm	3.0, 3.7, 5.0, 6.0 mm	Similar
Length	5.4 mm	6.6, 7.1 mm	Similar
Raw material	Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy	Identical
Connection Interface	Internal Conical Connection	Internal Conical Connection	Identical
Surface Treatment	Machined	Anodizing	Similar
Sterilization	Non-sterile; Steam sterilization prior to use	Non-sterile; Steam sterilization prior to use	Identical
Single Use	Yes	Yes	Identical
Restoration type	Single & Multi	Single & Multi	Identical
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Identical
Principle of Operation	Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.	Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.	Identical
SE	The subject device has the same intended use, principle of operation, material, connection interface, and similar design as the predicate device, and there are slightly different diameter and length. However, the diameter and length range of the subject device is within the range of the predicate device. However, this diameter and length range is to meet each patient		

	SUBJECT Device	**Primary PREDICATE Device (K182448)**	**Significant Difference**
Manufacturer	**highness Co., Ltd.**	**MegaGen Implant Co., Ltd.**	–
	needs and does not raise an issue in performance or safety since the size difference is very minor. The other difference is in surface treatment, but we already presented multiple predicate device for anodizing in the other component comparison charts. Therefore, it is substantial equivalent.		

IX. NONCLINICAL TEST

The following performance data was provided in support of the substantial equivalence determination.

Fatigue

Dynamic fatigue testing mechanical testing of the proposed Highness Implant System was performed in accordance with ISO 14801:2016, “Dentistry – Implants – Dynamic loading test for endosseous dental implants”, and FDA guidance on “Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Class II Special Controls Guidance Document for Industry and FDA Staff”. The test articles were able to withstand 5,000,000 cycles without failure under substantially equivalent loading to the cited primary predicate device cleared under K182448.

SLA Surface Treatment

The Highness Implant System utilizes an SLA (Sand-blasted, Large grit, Acid-etched) surface treatment for its fixtures. Cleaning validation and SEM/EDS (Scanning Electron Microscopy/Energy Dispersive X-ray Spectroscopy) analysis were performed on the proposed device to ensure the removal of any particles or chemicals used during the process. The SEM/EDS analysis confirms that no elements other than titanium were found on the surface of the implant.

Biocompatibility

Biocompatibility classification is based on the FDA Guidance Use of International Standard ISO 10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.”

The subject devices are classified as the implant medical devices, tissue/bone, long-term exposure (>30 days).

The subject devices have fulfilled all testing required per ISO 7405:2018, “Dentistry – Evaluation of biocompatibility of medical devices used in dentistry”, ISO 10993-1:2018, “Biological evaluation of medical devices – Part 1: Evaluation and testing” and the FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Cytotoxicity testing was conducted as per ISO 10993-5:2019, “Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity”. Cytotoxicity testing was conducted as per ISO 10993-5:2009, “Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity”.

Sterilization and Shelf Life

Similar to the Predicate Devices, the Highness Implant System is packaged in an aluminum pouch and supplied sterile and non-sterile.

The non-sterile abutments used in the surgery must be sterilized by the end user, prior to use, as stated in the IFU. User moist heat sterilization validation for the subject non-sterile devices was conducted according to, ISO 17665-1:2006, “Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices”, and ISO/TS 17665-2:2009, “Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1” and demonstrated a SAL of 10^{-6}.

The sterile implants (fixtures), following to gamma sterilization and packaging were subjected to sterile barrier testing to validate a shelf life of 5 years according to ISO 11607-1:2019, “Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems” and ISO 11607-2:2019, “Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes” confirm the stability and effectiveness of the packaging of the sterilized product during the shelf life, by evaluating changes due to accelerated aging, according to ASTM F1980-21, “Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices”.
For the sterile implants, gamma sterilization validation of the fixtures was performed in accordance with ISO 11137-1:2006, “Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices”, ISO 11137-2:2013, “Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose”, and ISO 11137-3:2017, “Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects of development, validation and routine control”.
In addition, for sterile fixtures, bacterial endotoxin testing was performed on sterile devices in accordance with ANSI/AAMI ST72:2019, "Bacterial Endotoxins - Test Methods, Routine Monitoring, And Alternatives To Batch Testing" using the Limulus Amebocyte Lysate (LAL) pyrogen test method at a test limit of 20 EU/device.

A non-clinical worst-case MRI review was performed to evaluate the subject device components in the MRI environment using scientific rationale and published literature (e.g., *Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795*), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. The rationale addressed parameters according to the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment”, including magnetically induced displacement force and torque.

X. CLINICAL TESTS

This 510(k) does not include data from clinical tests.

XI. CONCLUSIONS

The above information supports that the Highness Implant System is as safe and effective as the predicate devices. Although there are minor design differences between the subject and predicate devices, the review supports that these differences do not raise new questions of safety and effectiveness. Therefore, it is concluded that the Highness Implant System is substantially equivalent to the Predicate Devices.