Oneday Biotech Co., Ltd.
% April Lee
Consultant
Withus Group Inc
106 Superior
Irvine, California 92620

February 21, 2024

Re: K231753
Trade/Device Name: Oneday Implant Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 24, 2024
Received: January 24, 2024

Dear April Lee:

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.

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,

Andrew I. Steen -S

Andrew I. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231753

Device Name
Oneday Implant Abutment

Indications for Use *(Describe)*
Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.

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.

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510(K) Summary

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Device Information

- Trade Name: Oneday Implant Abutment
- Common Name: Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 872.3630
- Device Class: Class II
- Date Prepared: 02/21/2024

Predicate Devices:

Primary Predicate

- K211090, ZENEX Implant system

Reference devices

- K192294, I Do by I Do Biotech Co., Ltd.
- K122519, DIO UF HSA INTERNAL SUB-MERGED IMPLANT SYSTEM by DIO CORPORATION
- K161689, OSSTEM Implant System – Abutment by OSSTEM IMPLANT Co., Ltd.

Indication for Use:

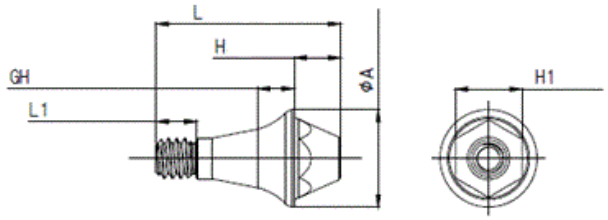
Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.

Device Description:
The Oneday Implant Abutment is a material for dental surgery and is an abutment used to support and maintain prosthetic restored teeth in case of partial or total loss of teeth. It is used in combination with a fixture implanted in the jawbone.

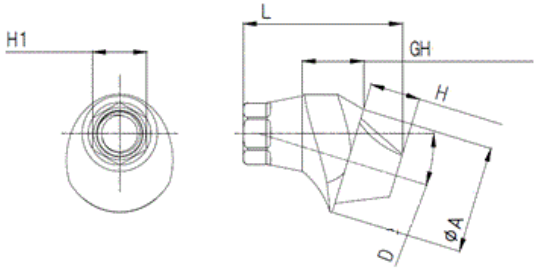
The compatible Fixture with the subject abutment system is below:

K number	Device Component	Diameters (Ø)	Lengths (mm)
K192294	Fixture-S	3.8	8.5/10.0/11.5/13.0/15.0
		4.0	7.3/8.5/10.0/11.5/13.0/15.0
		4.5	7.3/8.5/10.0/11.5/13.0/15.0
		5.0	7.3/8.5/10.0/11.5/13.0/15.0
		5.5	7.3/8.5/10.0/11.5
		6.0	7.3/8.5/10.0
		7.0	7.3/8.5/10.0
	Fixture-MT ACTIVE	3.8	8.5/10.0/11.5/13.0/15.0
		4.0	7.3/8.5/10.0/11.5/13.0/15.0
		4.5	7.3/8.5/10.0/11.5/13.0/15.0
		5.0	7.3/8.5/10.0/11.5/13.0/15.0
		5.5	7.3/8.5/10.0/11.5
		6.0	7.3/8.5/10.0
		7.0	7.3/8.5/10.0

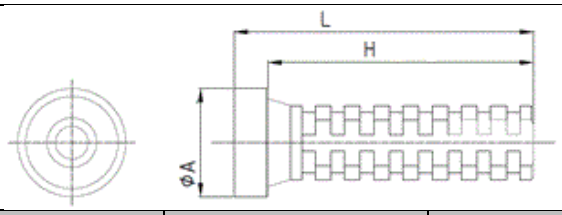
The dimensions of abutments are as following:



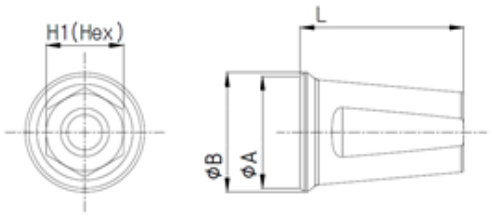
Device Name	Ø D	GH (mm)	H(mm)	L(mm)	L1(mm)	H1(mm)
Multiunit Straight Abutment	Ø4.8	0.8/1.8/2.8/3.8/4.8	2.3	8.1/9.1/10.1/11.1/12.1	1.8	3.3
	Ø4.8	0.8/1.8/2.8/3.8/4.8	2.3	8.6/9.6/10.6/11.6/12.6	2.0	3.3



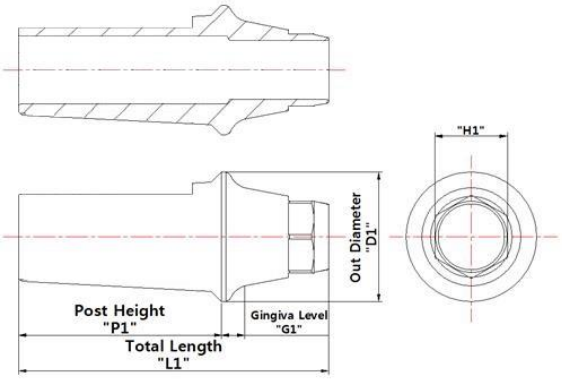
Device Name	Ø D	GH (mm)	H(mm)	Angle (º)	L(mm)	H1(mm)
Multiunit Angled Abutment	Ø 4.9	2.3/2.8/3.3/3.8/4.8	2.3	17,30	6.856-9.276	2.08/2.48



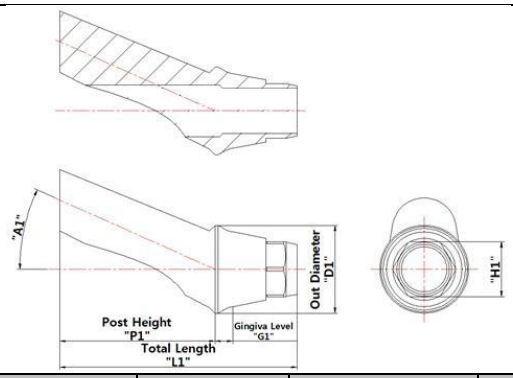
Device Name	Ø D	H(mm)	L(mm)
Multiunit Temporary Cylinder	Ø4.8	11.8	13.3



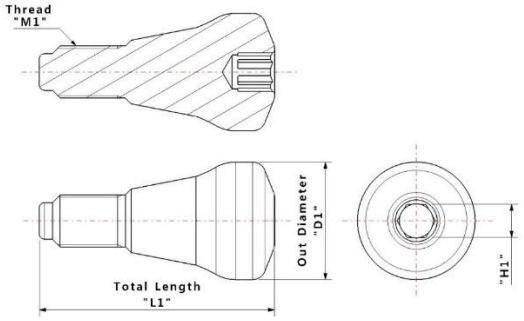
Device Name	Ø D	L(mm)	H1(mm)
Multiunit Ti Cylinder (Hex)	Ø4.8	7	3.31
Multiunit Ti Cylinder (Non-Hex)	Ø4.8	7	-



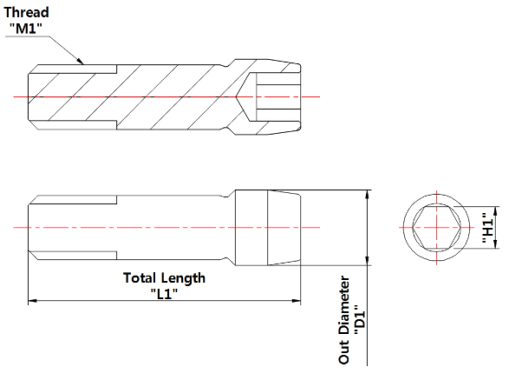
Device Name	Ø D	G1 (mm)	L1(mm)	P1(mm)	H1(mm)
Transfer Abutment (Hex)	Ø 4/4.5/5/5.5/6/7/8	0.8/1.8/2.8/3.8/ 4.8/5.8/6.8	7.7/8.7/9.7/10.7/ 11.7/12.7/13.7	4	2.495
	Ø 4/4.5/5/5.5/6/7/8	0.8/1.8/2.8/3.8/ 4.8/5.8	9.2/10.2/11.2/12.2/ 13.2/14.2	5.5	2.495
	Ø 4/4.5/5/5.5/6/7/8	0.8/1.8/2.8/3.8/ 4.8	10.7/11.7/12.7/ 13.7/14.7/	7	2.495
Transfer Abutment (Non-Hex)	Ø 4/4.5/5/5.5/6/7/8	0.8/1.8/2.8/3.8/ 4.8/5.8/6.8	7.7/8.7/9.7/10.7/ 11.7/12.7/13.7	4	-
	Ø 4/4.5/5/5.5/6/7/8	0.8/1.8/2.8/3.8/ 4.8/5.8	9.2/10.2/11.2/12.2/ 13.2/14.2	5.5	-
	Ø 4/4.5/5/5.5/6/7/8	0.8/1.8/2.8/3.8/ 4.8	10.7/11.7/12.7/ 13.7/14.7/	7	-



Device Name	Ø D	G1 (mm)	L1(mm)	P1(mm)	H1(mm)	Angle (º)
Angled Abutment (Hex)	Ø4/4.5/5/5.5/6/7/8	0.8/1.8/2.8/3.8	9.7/10.7/11.7/12.7	6	2.495	15,25
Angled Abutment (Non-Hex)	Ø4/4.5/5/5.5/6/7/8	0.8/1.8/2.8/3.8	9.7/10.7/11.7/12.7	6	-	15,25



Device Name	Ø D	L1 (mm)	H1(mm)
Healing Abutment	Ø4/4.5/5/5.5/6/6.5/7/7.5/8	7/8/9/10/11/12/13/14/15/16/17	1.2
	Ø4.2/4.7	8.3/9.3/11.3	1.2
Abutment Screw	Ø2.3	8.3	1.2



Device Name	Ø D	L1 (mm)	H1(mm)
Abutment Screw	Ø2.3	8.3	1.2

Tolerance of dimension shall be within ± 1% range.

The Abutments have below featured:

Name	Uses	Surface	Connection
Multiunit Straight Abutment	It is an abutment used when manufacturing screw retaining prosthesis in multiple cases.	N/A	Screw Retained, Internal Hex
Multiunit Angled Abutment		N/A	Internal Hex
Multiunit Temporary Cylinder	This product is an abutment for casting Use temporary	N/A	Multi abutment
Multiunit Ti Cylinder	It is an abutment for manufacturing combination maintenance type prosthesis by taking an abutment level impression	N/A	Screw Retained
Transfer Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function.	N/A	Internal Hex
Angled Abutment	The Abutment is connected with fixture and it supports prosthesis which restores tooth function		
Healing Abutment	The healing Abutment is used for protecting inner hole of fixture and adjusting the appropriate height during the healing period	N/A	Screw Retained
Abutment Screw	Connection body to connect abutment to fixture	N/A	Screw Retained

The subject abutments are provided non-sterile.

Materials:

- All products are fabricated from Ti-6Al-4V of ASTM F136

Summaries of Technological Characteristics & Substantial Equivalence Discussion

Multiunit Straight Abutment

	Subject Device	Primary Predicate
K number	K231753	K211090
Manufacturer	Oneday Biotech Co., Ltd.	Izenimplant Co., Ltd.
Trade Name	Oneday Implant Abutment	ZENEX Implant System
Model	Multiunit Straight Abutment	Multi Abutment
Indications for Use	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.	ZENEX Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.
Design		
Diameter(Ø)	4.8	4.8
Length(mm)	8.1, 8.6, 9.1, 9.6, 10.1, 10.6, 11.1, 11.6, 12.1, 12.6	8.5/ 10/11.5/13/15
Angle	0°	0°
Surface Treatment	Non-Coating	Non-Coating
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, general design, surface treatment, material, abutment connection, diameter, and sterilization method. The differences between the two devices are abutment design and lengths. The differences don't impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Multiunit Angled Abutment

	Subject Device		Primary Predicate	
K number	K231753		K211090	
Manufacturer	Oneday Biotech Co., Ltd.		Izenimplant Co., Ltd.	
Trade Name	Oneday Implant Abutment		ZENEX Implant System	
Model	Multiunit Angled Abutment		Multi Abutment	
Indications for Use	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.		ZENEX Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.	
Design	Hex	Non-Hex	Hex	Non-Hex
				
Connection Type	Hex, Non-Hex		Hex, Non-Hex	
Diameter(Ø)	4.9		4.83	
Length (mm)	6.856, 7.267, 7.276, 7.347, 7.356, 7.767, 7.847, 8.282, 8.356, 8.847, 8.767, 8,776, 9.276		7.05, 7.52, 8.05, 8.52, 9.05, 9.52, 10.05, 10.52,	

Angle	17°, 30°	17°, 30°
Surface Treatment	Non-Coating	Non-Coating
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, general design, surface treatment, material, abutment connection, and sterilization method. The differences between the two devices are abutment design and dimensions. The differences don't impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Multiunit Temporary Cylinder

	Subject Device	Primary Predicate
K number	K231753	K211090
Manufacturer	Oneday Biotech Co., Ltd.	Izenimplant Co., Ltd.
Trade Name	Oneday Implant Abutment	ZENEX Implant System
Model	Multiunit Temporary Cylinder	Multi Temporary Cylinder
Indications for Use	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.	ZENEX Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.
Design		
Diameter(Ø)	4.8	4.8
Length(mm)	13.3	12
Angle	0°	0°
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, general design, diameter, surface treatment, material, abutment connection, and sterilization method. The differences between the two devices are abutment design and length. The differences don't impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Multiunit Ti Cylinder

	Subject Device	Primary Predicate
K number	K231753	K211090
Manufacturer	Oneday Biotech Co., Ltd.	Izenimplant Co., Ltd
Trade Name	Oneday Implant Abutment	ZENEX Implant System
Model	Multiunit Ti Cylinder	Multi Ti Link Cylinder
Indications for Use	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.	ZENEX Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.

Design		
Connection Type	Hex, Non-Hex	Non-Hex
Diameter(Ø)	4.8	4.8
Length (mm)	7.0	12.0
Angle	0°	0°
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, general design, diameter, surface treatment, material, abutment connection, and sterilization method. The differences between the two devices are abutment design and length. The differences don't impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Transfer Abutment

	Subject Device	Reference Device
K number	K231753	K161689
Manufacturer	Oneday Biotech Co., Ltd.	Osstem Implant Co., Ltd.
Trade Name	Oneday Implant Abutment	Osstem Implant System - Abutment
Model	Transfer Abutment	Transfer Abutment
Indications for Use	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.	The OSSTEM Implant System -Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Design		
Connection Type	Hex, Non-Hex	Hex, Non-Hex
Diameter(Ø)	4, 4.5, 5, 5.5, 6, 7, 8	4.6, 5.0, 6.0, 7.0
Lengths (mm)	7.7, 8.7, 9.2, 9.7, 10.2, 10.7, 11.2, 11.7, 12.2, 12.7, 13.2, 13.7, 14.2, 14.7	7.5, 8.5, 9.0, 9.1, 9.5, 10.0, 10.6, 11.0, 11.1, 11.5, 11.6, 12.0, 12.1, 12.5, 12.6, 13.0, 13.1, 13.5, 13.6, 14.0, 14.5, 14.6
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Surface Treatment	Non-Coating	Non-Coating
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, general design, diameter, material, abutment connection, and sterilization method. The differences between the two devices are abutment design and length. The differences don't impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Angled Abutment

	Subject Device	Reference Device
K number	K231753	K122519
Manufacturer	Oneday Biotech Co., Ltd.	DIO Coporation
Trade Name	Oneday Implant Abutment	DIO UF HAS INTERNAL SUB-MERGED IMPLANT
Model	Angled Abutment	Angled Abutment
Indications for Use	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.	The DIO UF HAS Internal Sub-Merged Implant System is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units′ prosthetic attachment to restore a patient′s chewing function. The smaller (Ø3.8- Ø 5.5) implants ca be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability is achieved with appropriate occlusal loading. The larger (Ø 5.0- Ø 7.0) implants can be placed with a conventional two stage surgical process with an option for transmucosal healing and are indicated for the molar region with delayed loading.
Design		
Hex	Hex, Non-Hex	Hex, Non-Hex
Diameter(Ø)	4, 4.5, 5, 5.5, 6, 7, 8	4.5, 5.5
Length (mm)	9.7, 10.7, 11.7, 12.7 mm	-
Angle	15°, 25°	15°, 25°
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, design, material, and sterilization method. The difference between two devices is design and dimensions. These differences do not impact product′s fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Healing Abutment

	Subject Device	Primary Predicate
K number	K231753	K211090
Manufacturer	Oneday Biotech Co., Ltd.	Izenimplant Co., Ltd.
Trade Name	Oneday Implant Abutment	ZENEX Implant System
Model	Healing Abutment	Healing Abutment
Indications for Use	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.	ZENEX Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the molar region.
Design		
Diameter(Ø)	4, 4.2, 4.5, 4.7, 5.5, 6, 6.5, 7, 7.5, 8	4.0~9.0
Length (mm)	7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17	-

Angle	0°	0°
Surface Treatment	Non-Coating	Non-Coating
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, general design, material, abutment connection, surface treatment and sterilization method. The differences between the two devices are abutment design and dimensions. The differences don't impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Abutment Screw

	Subject Device	Reference Device
K number	K231753	K161689
Manufacturer	Oneday Biotech Co., Ltd.	OSSTEM Implant Co., Ltd.
Trade Name	Oneday Implant Abutment	OSSTEMImplant System - Abutment
Model	Abutment Screw	Abutment Screw
Indications for Use	Oneday Implant Abutment is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Implants with diameters larger than 5 mm are intended to be used in the molar region.	The OSSTEM Implant System -Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Design		
Diameter(Ø)	2.3	2.0, 2.05, 2.2, 2.3, 2.5
Length(mm)	8.3	3.35, 5.6, 7.5, 8.35, 9.6, 10.2
Material	Ti 6Al 4V ELI(ASTM F136)	Ti 6Al 4V ELI(ASTM F136)
Surface Treatment	Non-coating	Non-coating
Sterilization	End User Sterilization	End User Sterilization
Comparison	The Subject Device and primary predicate have same characteristics such as indications for Use, general design, material, abutment connection, surface treatment and sterilization method. The differences between the two devices are abutment design and dimensions. The differences don't impact product's fundamental technologies; therefore, subject device and predicate device are substantially equivalent.	

Non-Clinical Test Data
Below tests were performed on subject device:

- Fatigue Testing under the worst-case scenario according to ISO 14801:2016
- End User Sterilization Validation Test Report on Abutments according to ANSI/AAMI ST79, ISO 17665-1, ISO 17665-2, ISO 11737-1, ISO 11737-2, and ISO 11138-1

Below tests were performed on a worst-case test article with the same material composition, manufacturing, and sterilization and leveraged for the subject device:

- Biocompatibility testing on Abutments made with Ti-6Al-4V ELI according to ISO 10993-1:2009, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-6:2007, ISO 10993-10:2010 and ISO 10993-11:2006

The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the predicate device.

The end user sterilization test was performed on abutment that is not cleared but it can be leveraged for the subject device because the product category, material, manufacturing process, facility, and packaging of the both products are exactly same.

The Biocompatibility Test was conducted on abutment made of Ti-6Al-4V ELI and leveraged for the subject device because both products are manufactured with same materials and manufacturing process. It demonstrates that the subject device is biocompatible and substantial equivalence with the predicate.

The Fatigue Testing was performed under worst case scenario according to ISO 14801.

MR Environment Condition
Non-clinical worst-case MRI review was performed to evaluate the metallic devices 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, dental abutments, and fixation screws) and material composition.
Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

Clinical testing was not necessary to establish substantial equivalency of the device.

Conclusion
Oneday Implant Abutment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, Oneday Implant Abutment and its predicates are substantially equivalent.