March 5, 2024

Modern Dental Laboratory (DG) Co., Ltd.
Robin Liu
Compliance Manager
Room 102 & 1102 & Floor 4-10, Block 1 Modern Dental Industrial Park
NO. 7 Nantou, Songshan Lake Hi-Tech Industrial Zone
Dongguan, Guangdong 523000
CHINA

Re: K231210
Trade/Device Name: DGA Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 5, 2024
Received: February 5, 2024

Dear Robin Liu:

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.*

Submission Number *(if known)*

K231210

Device Name

DGA Abutment

Indications for Use *(Describe)*

DGA Abutment is a patient-specific prosthetic component directly connected to the endosseous dental implant (details as below) is intended for use as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
Brand ：Straumann
System：Tissue Level (ST)
Platform & Implant body diameter ：RN （4.1mm,4.8mm)， WN (4.8mm)
510(k) number：K122855

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 5. 510(k) Summary

## 5.1 Submitter Information


| | |
|---|---|
| Company Name: | Modern Dental Laboratory (DG) Co.,Ltd. |
| Company Address: | Room 102&1102&Floor 4-10,Block 1 Modern Dental Industrial Park, No.7 Nantou, Songshan Lake Hi-Tech Industrial Zone 523000 Dongguan,Guangdong People's Republic of China |
| Company Phone: | 0769-22899211 |
| Contact Person: | Robin Liu |
| Email: | Robin.liu@ moderndentallab.com |
| Date Prepared | March 5,2024 |


## 5.2 Device Identification

| | |
|---|---|
| Device Model Name: | DGA Abutment |
| Classification Name: | Endosseous Dental Implant Abutment |
| Regulation Number: | 872.3630 |
| Product Code: | NHA |
| Class | II |
| Panel | Dental |

## 5.3 Predicated Devices

| | |
|---|---|
| Primary Predicate Device: | K213961 |
| Reference Device: | K151295，K142813 |

## 5.4 Device Description

DGA Abutment is endosseous implant abutment which is placed into a corresponding dental implant to provide support for a prosthetic restoration. DGA Abutment is made of titanium grade Ti-6Al-4V ELI (meets ASTM Standard F136). The DGA Abutment is mounted on the implant with a screw. Each abutment is supplied with two identical screws which are used for:

a. For fixing into the endosseous implant.
b. For dental laboratory use during fabrication of restoration.

The screw is also made of titanium grade Ti-6Al-4V ELI (meets ASTM Standard F136).

DGA Abutment is compatible with the following implant

| Brand | System | Platform | Implant body diameter | 510(k) number |
|---|---|---|---|---|
| Straumann | Tissue Level (ST) | RN | 4.1mm,4.8mm | K122855 |
| | | WN | 4.8mm | K122855 |

The range of design parameters of DGA Abutment please refer to the following sheet.

| Abutment post height (length above collar/ gingival height) | Angulation | Abutment diameter | Wall thickness | Gingival height |
|---|---|---|---|---|
| 4-9 mm (±0.2mm) | 0° (±0.1°) | 4-7 mm (±0.03mm) | ≥0.4mm (±0.05mm) | 0-7mm (±0.2mm) |

**5.5 Indication for Use**

DGA Abutment is a patient-specific prosthetic component directly connected to the endosseous dental implant (details as below) and is intended for use as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

| Brand | System | Platform | Implant body diameter | 510(k) number |
|---|---|---|---|---|
| Straumann | Tissue Level (ST) | RN | 4.1mm,4.8mm | K122855 |
| | | WN | 4.8mm | K122855 |

**5.6 Technological Characteristics**

- Performance Specification

The DGA Abutment is designed to serve as a connection component between a dental implant and a dental prosthesis and to remain for indefinitely in the oral cavity. As such it must fulfil the following –

a. Made with a biocompatible material suitable for permanent mucosal contact.
b. Provide an aesthetic profile from the implant up to the dental prosthesis.
c. Provide sufficient strength to withstand masticatory forces.

- Mechanical Properties

The fatigue testing of the DGA Abutment was conducted in accordance with ISO 14801: 2016 Dentistry -- Implants -- Dynamic loading test for endosseous dental implants and FDA guidance " Class II Special Controls Guidance Document: Rootform Endosseous Dental Implants and Endosseous Dental Implant Abutments", the finished assembled implant,abutment and screw systems were used to tested.

- Material Properties

The DGA Abutment is made of titanium grade Ti-6Al-4V which meets ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications.To further confirm finished DGA Abutment's safety, some biocompatibility testing were conducted as per ISO 10993 series of standards, such as cytotoxicity, sensitization and irritation, these tests suggest that DGA Abutment has no cytotoxicity, no sensitization and no irritation and is safety for patient.

- Manufacturing Process

The DGA Abutment should be machined with computer numerical control equipment and tungsten carbide cutting tools ,and water soluble coolants should be employed during the machining process. Finished DGA Abutments should be thoroughly rinsed with clean water to remove the coolants.

DGA Abutment is delivered non-sterile for single use and must be cleaned and sterilized prio to use.The sterilization validation was carried out according to ISO 17665-1:2006. The recommended sterilization method is provided as below:

| Method | Moist heat sterilization |
|---|---|
| Cycle | Pre-vacuum |
| Temperature | 132℃(270° F) |
| Exposure time | 4 min |
| Drying Time | 20 min |

- Mode of Action

The mechanism of action is exactly same with the primary predicate device and reference device, and supports a determination of substantial equivalence.The infrastructure of the DGA Abutment is connected with the implant using screw-retained, and the superstructure of the DGA Abutment is connected with the dental prosthesis by cemented.The DGA Abutment is surgically placed in the maxillary and mandibular arches for supporting the dental restorations to restore patient's chewing function.

- MR Compatibility

Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., 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 to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The 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.

- Reverse Engineering Analysis

Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were performed, including an assessment of maximum and minimum dimensions of critical design aspects, tolerances, and cross-sectional images of the submission device and compatible OEM implant body, OEM abutment, and OEM fixation screw. The testing demonstrated implant to abutment compatibility and has established substantial equivalency of the proposed device with predicate

devices.Static and fatigue testing according to ISO 14801 were performed on worst case scenario. The results of the above tests have met the criteria of the standards and demonstrated the substantial equivalence with the primary predicate.

**5.7 Risk Management**

The risks to health have been identified, identified risks generally associated with the use of the DGA Abutment. The identifying approach of risk is specified as per the standard ISO 14971: 2019 Medical devices - Application of risk management to medical deices and ISO TR 24971: 2020 Medical devices - Guidance on the application of ISO 14971.

### 5.8 Substantial Equivalence Comparison

| Elements | Subject Device | Primary Predicate Device | Reference Device | Reference Device | Explanation |
|---|---|---|---|---|---|
| **Name** | DGA Abutment | TruAbutment DS | Biodenta Customised Abutment -Titanium | Duplex Abutment | - |
| **510(k) Number** | New device | K213961 | K151295 | K142813 | - |
| **Manufacturer** | Modern Dental Laboratory (DG) Co., Ltd. | TruAbutment Inc. | Biodenta Swiss AG | Biogenesis Co., Ltd. | - |
| **Regulation Number** | 21 CFR 872.3630 | 21 CFR 872.3630 | 21 CFR 872.3630 | 21 CFR 872.3630 | Same |
| **Classification Name** | Endosseous Dental Implant Abutment | Endosseous Dental Implant Abutment | Endosseous Dental Implant Abutment | Endosseous Dental Implant Abutment | Same |
| **Product Code** | NHA | NHA | NHA | NHA | Same |
| **Device Class** | Class II | Class II | Class II | Class II | Same |
| **Indication for Use** | DGA Abutment is a patient-specific prosthetic component directly connected to the endosseous dental implant (details as below) and is intended for use as a support for | TruAbutment DS is a patient-specific CAD/CAM abutment, directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. It is compatible with the following | The Biodenta Customized Abutment-Titanium is intended for use with dental implants as a support for single or multiple tooth prostheses in the | The Biogenesis Implant System - Kisses is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple -unit restorations including; cemented retained, | Same. Slightly difference in description, however the content is substantial equivalence. |

| | | | | | |
|---|---|---|---|---|---|
| | single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.<br>Brand: Straumann<br>System: Tissue Level (ST)<br>Platform & Implant body diameter: RN (4.1mm, 4.8mm), WN (4.8mm)<br>510(k) number: K122855 | systems:<br>• Straumann Tissue Level Implant (K122855, K202942): 4.1(RN), 4.8(RN), 6.5(WN) mm | maxilla or mandible of a partially or fully edentulous patient. | screw retained,or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Biogenesis Implant System - Kisses is for single and two stage surgical procedures.It is for delayed loading | |
| **Abutment and Screw material** | Ti-6Al-4V ELI | Ti-6Al-4V ELI | Ti-6Al-4V ELI | Ti Gr.4 | The material of subject device is same as that of predicate device and reference device K151295. |
| **Abutment fixation** | Screw-retained | Screw-retained | Screw-retained | Screw-retained | Same |
| **Abutment Angulation** | 0°<br>(±0.1°) | Max 25º | Max 30º | straight | the subject's allowed angulation is smaller than that of predicate /reference( K151295) device, and is same as that of reference device K142813. |
| **Abutment Diameter** | 4-7 mm<br>(±0.03mm) | 5.2-8.0 mm | 4.5-15 mm | 4.0-6.5mm | Belong to patient - specific,slightly |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | difference in parameter in diameter, however it doesn't affect the substantial equivalence. |
| **Abutment Post Height (length above collar/ gingival height)** | 4-9 mm (±0.2mm) | 4.0-7.0 mm | 5.0 - 12.3 mm | 4.0-7.0mm | Belong to patient -specific,slightly difference in parameter in height, however it doesn't affect the substantial equivalence. |
| **Wall thickness** | Min 0.4mm (±0.05mm) | Min 0.4mm | Unknown | unknown | Same as predicate device |
| **Gingival height** | 0-7mm (±0.2mm) | Unknown | Unknown | 1.0-7.0mm | Belong to patient -specific,slightly difference in parameter in height, however it doesn't affect the substantial equivalence. |
| **Installation procedure** | 1. The final DGA Abutment is attached to the implant using the corresponding dental screw.<br>2. The dental screw is | a. After osseointegration has been successfully achieved for the fixture, design an appropriate CAD/CAM custom abutment suitable to the oral environment.<br>b. Reproduce the configuration | An abutment screw provided by Biodenta is used to secure the abutment to the implant, whereas the prosthesis is custom | It's not available from public database. | Subject device is substantial equivalence to primary predicate and reference device (K151295) . Slightly |

| | | | | | |
|---|---|---|---|---|---|
| | tightened in the recommended torque<br>3. In order to obtain the recommended torque, a dental torque wrench with a suitable screw driver must be used in accordance with the relevant manufacturer‘s instructions<br>4. The screw channel must always be sealed after the abutment is attached to the implant. | of the oral cavity of the patient through impression and send the impression to a dental laboratory to fabricate the final prosthesis. Once the final prosthesis fabrication is completed, deliver it to the patient to improve their masticating and aesthetic functions.<br>c. When affixing an abutment onto a fixture, the recommended torque value is equivalent to the manufacturers’ value for the respective implant system. The torque value should be determined based on the clinical assessment of the bone quality, fixture dimensions, and prosthesis type, etc. | made and cement-retained on the abutment. The abutment screw should be tightened with a manual torque wrench according to the implant manufacturer’s specifications. | | difference in description, however the content is substantial equivalence. |
| **CAD/CAM Processing** | Milled at Modern Dental Laboratory under QSR control. | All digitally designed abutments and/or coping for use with the TruAbutment DS abutments are intended to be sent to a TruAbutment-validated milling center for manufacture. | Milled in Biodenta milling center under QSR control. | It’s not available from public database. | Subject device is substantial equivalence to primary predicate and reference device (K151295) |
| **Compatible Implant** | Straumann Tissue | Straumann Tissue Level Implant | Dentsply, AstraTech OsseoSpeed | Biogenesis Implant System - Kisses | Subject device and primary predicate |

| | | | | | |
|---|---|---|---|---|---|
| **System** | Level Implant (K122855): 4.1(RN), 4.8(RN) ,4.8(WN) mm | (K122855, K202942): 4.1(RN), 4.8(RN), 6.5(WN) mm | Biomet 3i, Certain Internal<br>Zimmer, Screw Vent<br>Nobel Biocare,Nobel Replace<br>Nobel Biocare,Nobel Active<br>Straumann, Bone Level<br>BioHorizons,Internal<br>Osstem, GS/TS<br>Biodenta, Bone Level and Tapered | | device both are compatible with Straumann Tissue Level Implant |
| **Sterilization** | Non-sterile | Non-sterile | Non-Sterile | Non-Sterile | Same |

**5.9 Substantial Equivalence Conclusion**

The DGA Abutment is substantially equivalent to the primary predicate device and the reference devices in terms of indication for use, technical characteristics and function. Although there are slightly differences in size parameter of devices, these differences are very minor not affecting substantial equivalence.

Therefore, the subject device, the predicate device and the reference devices are substantial equivalence.