February 27, 2020

Rodo Medical, Inc.
% Randy Prebula
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, District of Columbia 20004

Re: K193274
Trade/Device Name: Rodo Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 10, 2020
Received: February 10, 2020

Dear Randy Prebula:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K193274

Device Name

Rodo Abutment System

Indications for Use *(Describe)*

Rodo Abutment System is intended to be used in conjunction with compatible implant systems in the maxillary or mandibular arch to provide support for crowns, bridges or overdentures.

Compatible Systems		
Implant Line	OEM Platform Size	OEM Body Size
Straumann Bone Level	NC, RC	3.3, 4.1, 4.8
Neodent Drive CM	3.5, 4.3, 5.0	3.5, 4.3, 5.0
Neodent Titamax CM	3.5, 3.75, 4.0, 5.0	3.5, 3.75, 4.0, 5.0
Neodent Alvim CM	3.5, 4.3, 5.0	3.5, 4.3, 5.0
NobelActive	3.0, NP, RP, WP	3.0, 3.5, 4.3, 5.0, 5.5
Nobel Replace Conical	NP, RP	3.5, 4.3, 5.0
NobelReplace Straight	NP, RP, WP	3.5, 4.0, 5.0
NobelReplace Tapered	NP, RP, WP, 6.0	3.5, 4.3, 5.0, 6.0
NobelSpeedy Replace	NP, RP, WP, 6.0	3.5, 4.0, 5.0, 6.0
Biohorizons Tapered Internal	3.0, 3.5, 4.5, 5.7	3.0, 3.4, 3.8, 4.6, 5.8
Biomet 3i Certain Internal	3.4, 4.1, 5.0, 6.0	3.25, 3.4, 4.1, 5.0, 6.0
Neodent GM	3.5	3.5, 3.75, 4.0, 4.3, 5.0, 6.0

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

X 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

Rodo Medical's Rodo Abutment System

(K193274)

Submitter:

Rodo Medical Inc.
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San Jose, CA 95119
Telephone: +1 (408) 245-7636
Fax: +1 (408) 338-6940

Contact Person: James Park, Vice President of R&D and Education

Date Prepared: February 27, 2020

Name of Device: Rodo Abutment System

Common or Usual Name: Endosseous dental implant abutment

Classification Name: Endosseous dental implant abutment

Regulation Number: 21 CFR 872.3630

Class: Class II

Product Code: NHA

Primary Predicate Device

Rodo Medical Abutment System, K160786

Reference Devices

Biomet Certain Internal Connection Implants, K122300, K062636, K063286, K063341, K061629, K100724, K111216

BioHorizons Tapered Internal Connection Implants, K121787, K071638, K073268, K143022, K071638, K093321, K073268

Neodent GM Connection Implants, K163194

Device Description

The purpose of this submission is to obtain U.S. premarket clearance for the Rodo Abutment System's use with three newly added compatible implant lines: Biohorizons Tapered Internal; the Biomet 3i Certain Internal; and the Neodent GM. With the exception of minor dimensional changes to the Rodo Abutments to accommodate the newly identified compatible implant lines, the Rodo Abutment System remains technologically identical to the predicate Rodo Abutment System.

The Rodo Abutment System includes the Rodo Abutment, Smileloc Sleeve, Titanium Coping, Temporary Cap, abutment screws, the Smileloc Activator (or Smileloc Remover) (all cleared under K160786) and Smilekey (cleared under K180609). The Smileloc Sleeve is used to lock and unlock the Titanium Coping for final restoration to or from the abutment. This makes the prosthesis removable. The Rodo Abutment System eliminates the need for an access hole on the occlusal surface of a screw-retained restoration and also eliminates the possibility of prosthetic screw loosening. The Smilekey is an induction heating device for dental prosthesis removal of the Smileloc Sleeve in the Rodo Abutment System. The Smilekey was cleared as an accessory to the Abutment System in K180609, and there have been no changes to the Smilekey since this clearance.

The Rodo Abutment is provided in five series designs (100 F, 200 P, 300 S, 400 M, 500 D) with the 200 P and 500 D series having angled abutments (17°, 30°), for a total of nine designs. The 300 S series is designed for limited occlusal space and the 400 M series is designed for large interproximal spaces. Abutments are available in sizes ranging from 3.0 mm to 6.0 mm depending on the compatible implant system in use. Designs are available with engaging and non-engaging implant-abutment interfaces.

Indications for Use

The Rodo Abutment System is intended to be used in conjunction with compatible implant systems in the maxillary or mandibular arch to provide support for crowns, bridges or overdentures.

Compatible Systems		
Implant Line	OEM Platform Size	OEM Body Size
Straumann Bone Level	NC, RC	3.3, 4.1, 4.8
Neodent Drive CM	3.5, 4.3, 5.0	3.5, 4.3, 5.0
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Biomet 3i Certain Internal	3.4, 4.1, 5.0, 6.0	3.25, 3.4, 4.1, 5.0, 6.0
Neodent GM	3.5	3.5, 3.75, 4.0, 4.3, 5.0, 6.0

Summary of Technological Characteristics

The predicate device and the subject device are technologically identical, with only minor dimensional changes to the Rodo Abutments to accommodate the newly identified compatible implant lines. These dimensional changes were conducted to accommodate the newly added implant interfaces for the three additional compatible implant lines: Biohorizons Tapered Internal; the Biomet 3i Certain Internal; and the Neodent GM. No other changes were made other than referenced minor dimensional changes to add compatibilities to the newly added implant interfaces.

The predicate device and the subject device are abutments used in conjunction with compatible implant systems in the maxillary or mandibular arch to provide support for crowns, bridges or overdentures.

All reference devices that are identified in this submission are for the 510(k) clearances of the newly compatible implant bodies.

Performance Data

The company has submitted non-clinical testing data to demonstrate via dimensional analysis and reverse engineering that the company's Rodo Abutment System is substantially equivalent to the predicate abutment system (previously cleared under K160786) and is compatible with the new implant interfaces identified in the indications for use. The company has also submitted fatigue test data for testing conducted in accordance with ISO 14801, *Dentistry – Implants – Dynamic loading test for endosseous dental implants*, for use of the Rodo Abutment System with the Biohorizons Tapered Internal, Biomet 3i Certain Internal, and Neodent GM implant lines.

The company also performed reverse engineering analysis for each of the three new compatible implant system interfaces. Reverse engineering was conducted for the original equipment manufacturer (OEM) implant bodies, OEM fixation screws, and OEM abutments. The reverse engineering testing approach followed is identical to that used in the previously cleared abutments (cleared under K160786).

The minor dimensional changes to the Rodo Abutments to accommodate the newly identified compatible implant lines did not necessitate re-testing for those tests completed and provided in the predicate 510(k) submission (e.g., sterilization validation, biocompatibility, electrical safety analysis, thermal properties testing, corrosion testing, and retention testing).

Conclusions

The subject device and the predicate device are technologically identical and include almost identical indications for use. The only difference is that the subject device expands the number of identified compatible implants and includes abutments that have been reverse engineered to interact with the new implant interfaces being identified. The subject device and predicate device abutments encompass the same range of physical dimensions, including diameter, gingival height, and angle of the abutments.

The data included in this submission demonstrate substantial equivalence to the predicate Rodo Abutments.