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

May 23, 2018

Re: K180609
Trade/Device Name: Rodo Smilekey
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 8, 2018
Received: March 8, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K180609

Device Name

Rodo Smilekey

Indications for Use *(Describe)*

The Rodo Smilekey is intended to be used with the Rodo Abutment System for removing prostheses compatible with Smileloc Sleeve by using induction heating.

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, Inc.'s

Rodo Smilekey (K180609)

Submitter

Company:	Rodo Medical, Inc.
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Contact Person:	Michael Parsons
Date Prepared:	May 10, 2018

Subject Device

Name of Device:	Rodo Smilekey
Classification Name:	Endosseous Dental Implant Abutment
Regulation:	21 C.F.R. § 872.3630
Regulatory Class:	Class II
Product Code:	NHA

Predicate Device

Company:	Rodo Medical, Inc.
Device Name:	Rodo Abutment System
510(k) Number:	K160786
Regulation:	21 C.F.R. § 872.3630
Product Codes:	NHA

Device Description

The Smilekey is an additional remover device intended for use with the predicate Rodo Abutment System (K160786). It is used to deliver induction energy to the Smileloc Sleeve. The Smilekey consists of a tip and handle that uses induction (alternating electromagnetic field) to deliver precise energy to the Smileloc. Only the end of the tip is inserted inside the patient's mouth while the handle is hand-held by the operator. The Smilekey is powered by a rechargeable lithium battery inside the handle. The handle also contains an electronic control board that regulates the entire operation, including LED indicators that let the operator know when energy is being applied to the Smileloc Sleeve and when the unlocking procedure has been completed.

Intended Use / Indications for Use

The Rodo Smilekey is intended to be used with the Rodo Abutment System for removing prostheses compatible with Smileloc Sleeve by using induction heating.

Performance Data

The following bench testing was conducted to demonstrate the performance of the Smilekey:

- Electrical safety testing according to AAMI/ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012
- EMC testing according to AAMI/ANSI/IEC 60601-1-2:2014
- Biocompatibility evaluation of the patient contacting materials
  - Identical Handle material to predicate Smileloc Activator (K160786)
  - FDA guidance document titled, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'", issued on June 16, 2016
  - Cytotoxicity testing of the tip housing material according to ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- Cleaning and disinfection testing with simulated challenge soiling and organism
  - FDA guidance document titled, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", issued on May 2, 2011
  - AAMI TIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
- Software verification and validation testing
  - FDA guidance document titled, "Content of Premarket Submission for Software Contained in Medical Devices", issued on May 11, 2005
- Battery testing according to IEC 62133:2012
- Usability testing according to IEC 60601-1-6 Edition 3.1 2013
- Thermal safety testing to evaluate the temperature rise on implant, abutment and restoration during the unlocking procedure using the Smilekey induction activator, to ensure that temperatures do not exceed established safety limits.
  - ASTM F2182–11 testing guidelines were used which included gel media and simulated use conditions.
  - The thermal safety limits were equivalent to the predicate Smileloc Activator (K160786).
  - The results demonstrated that the temperatures were within safe limits.

Substantial Equivalence

The proposed Rodo Smilekey and the predicate Smileloc Activator (part of the Rodo Abutment System K160786) have a similar intended use and similar indications of removing the Smileloc Sleeve from the Rodo Abutment. Both devices are intended to activate the Smileloc Sleeve to release a compatible prosthesis with the Rodo Abutment. Although the subject device uses induction heating instead of resistance heating, this difference in technological characteristics does not raise different questions of safety or effectiveness. Both devices deliver energy to increase the temperature of the Smileloc Sleeve. The induction energy is within safe levels for

the oral application. In addition, the performance of the Rodo Abutment System and the thermal safety was verified and validated using the same scientific methodology as the predicate device. In addition, bench testing of the subject device has demonstrated substantial equivalent performance to the predicate device.

Conclusions

The Smilekey is an additional remover device intended for use with the predicate Rodo Abutment System (K160786). Similar to the predicate Smileloc Activator, the Smilekey uses heat to activate and to remove the Smileloc Sleeve. Although the Smilekey has a different heating method when compared to the Smileloc Activator, this difference in technological characteristics does not raise different questions of safety or effectiveness. Performance bench testing of the Smilekey demonstrated equivalent performance as the predicate device. Thus, the Smilekey can be found substantially equivalent to the predicate device.

Table 1: Comparison of Subject and Predicate Devices

	Subject Device Rodo Smilekey	**Predicate Device Smileloc Activator of Rodo Abutment System (K160786)**	**Comparison**
Indications for Use	The Rodo Smilekey is intended to be used with the Rodo Abutment System for removing prostheses compatible with Smileloc Sleeve by using induction heating.	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.	The Indications for Use of the subject device is derived from the labeling of the Smileloc Activator component of the overarching Rodo Abutment System.
Heating Method	Induction heating	Resistance heating	Difference in heating method does not raise different questions of safety or effectiveness
Type of battery charge	Lithium Ion	Lithium Ion	Same
Is battery rechargeable?	Yes	No	Battery rechargeability does not raise additional questions of safety or effectiveness
Time needed for tip on crown to activate	5 seconds for acrylic restorations, 9 seconds for non-acrylic restorations (*e.g.*, lithium disilicate, zirconia)	15 seconds	Difference in activation time does not raise different questions of safety or effectiveness. Maximum implant and abutment temperatures reached during activation remain below safety limits.
Maximum implant/abutment temperature reached during activation	Maximum implant and abutment temperatures during activation remain below safety limits established by *AAMI/ANSI ES60601-1:2005/® 2012 and A1:2012, c1:2009/® 2012 and a2:2010/® 2012* and *Eriksson, AR et al.*	Maximum implant and abutment temperatures during activation remain below safety limits established by *AAMI/ANSI ES60601-1:2005/® 2012 and A1:2012, c1:2009/® 2012 and a2:2010/® 2012* and *Eriksson, AR et al*.	Same

	Subject Device Rodo Smilekey	**Predicate Device Smileloc Activator of Rodo Abutment System (K160786)**	**Comparison**
Type of indicators to inform the end user	LED	LED	Same
Regulation of energy delivery	Internal timer	Internal timer	Same
Type of barrier employed for infection control of device	FDA-cleared dental barrier sleeve	FDA-cleared dental barrier sleeve	Same