November 21, 2016

Rodo Medical, Inc.
c/o Ms. Linda Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real
Suite 400
San Diego, California 92130

Re: K160786
   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: October 21, 2016
   Received: October 24, 2016

Dear Ms. Linda Schulz:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for 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
Indications for Use

510(k) Number (if known)
K160786

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

<table>
<thead>
<tr>
<th>Implant Line</th>
<th>OEM Platform Size</th>
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<tbody>
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<tr>
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<td>3.5, 4.0, 5.0, 6.0</td>
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</tbody>
</table>

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
Rudo Medical, Inc.
Rudo Abutment System
K160786

November 21, 2016

ADMINISTRATIVE INFORMATION

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Executive Vice President

Representative/Consultant: Linda K. Schulz, BSDH, RDH
Kevin A. Thomas, PhD
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Fax: +1 (858) 792-1236
Email: lschulz@paxmed.com
kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Rudo Abutment System
Common Name: Endosseous dental implant abutment
Classification Name: Endosseous dental implant abutment
Classification Regulations: 21 CFR 872.3630, Class II
Product Code: NHA
Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate
K120414, OsseoSpeed™ Plus, Astra Tech AB

Reference Predicates

Abutment Design
K092341, Low Profile Abutment, Biomet 3i

Compatibility
K062129, P.004 Implants, Institut Straumann AG
K101945, Neodent Implant System, JGC Indústria e Comércio de Materiais Dentários SA
K123022, Neodent Implant System, JGC Indústria e Comércio de Materiais Dentários SA
K142260, NobelActive®, Nobel Biocare AB
INDICATIONS FOR USE

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.

DEVICE DESCRIPTION

The Rodo Abutment System includes the Rodo Abutment, Smileloc Sleeve, Silicone Seal, Titanium Coping, Temporary Cap, abutment screws, and Smileloc Activator (or Smileloc Remover). 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.

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 200 P and 500 D series are designed for multi-unit restorations only, 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 Ø 3.0 mm to Ø 6.0 mm depending on the compatible implant system in use. Designs are available with engaging and non-engaging implant-abutment interfaces.

PERFORMANCE DATA

Non-clinical testing data submitted or relied upon to demonstrate substantial equivalence included: steam sterilization validation according to ISO 17665-1 and ISO 17665-2, demonstrating a sterility assurance level (SAL) of 10⁶; biocompatibility testing according to ISO 10993-5 (cytotoxicity) and ISO 10993-10 (sensitization and irritation), demonstrating acceptable biocompatibility; electrical safety analysis according to AAMI / ANSI ES60601-1:2005/(R) 2012 and A1:2012, c1:2009/(R) 2012 and a2:2010/(r) 2012, IEC 60601-1-6, IEC 60601-1-2 and IEC 62366 and risk analysis according to ISO 14971, demonstrating acceptable electrical safety; thermal properties testing according to ASTM F2004, showing acceptable transition temperatures; corrosion testing according to ASTM G71 and ASTM F2129 and nickel leaching evaluation, showing acceptable corrosion resistance; retention testing, showing acceptable retention strength; reverse engineering and dimensional analysis of OEM devices, showing that the Rodo Abutment is compatible with corresponding OEM implants; and static and dynamic compression-bending testing according to ISO 14801, showing mechanical performance sufficient for its intended use.
CLINICAL DATA

A prospective multi-center clinical trial, designed to evaluate the safety and effectiveness of the Rodo Abutment System for dental implants, was conducted under an Investigational Device Exemption study according to FDA guidelines. The Rodo Abutment System was used with corresponding compatible implant systems. A total of thirty-four (34) subjects (17 male, 17 female), with previously implanted compatible implants ready for restoration, were enrolled at two study centers. Thirty-two subjects received Rodo Abutments and restorations. Three of these subjects each received four Rodo abutments as part of their full arch, immediate load treatment. In total, 41 Rodo Abutments were placed and restored.

Of the nine adverse events recorded over the duration of the study, two were abutment screw loosening (resolved by re-tightening the screw), one was separation of the crown from the coping due to inadequate bonding in the laboratory (resolved by re-bonding in the laboratory), and the remaining six events were not device related. No adverse events were related to the Smileloc sleeve or attachment of the prosthesis to the abutment.

The overall conclusion from the study was that the Rodo Abutment System provides an appropriate method of attaching prosthetic restorations to dental implant abutments. If necessary, it allows repeated removal of the restoration, as is the case for screw-retained restorations on dental implant abutments.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles to the predicate devices shown above.

Rodo Abutment System is substantially equivalent to the OsseoSpeed Plus implant system (K120414) and Low Profile Abutment (K092341). Rodo Abutment System has two coping designs for Smileloc-retained (Smileloc Sleeve) prostheses while OsseoSpeed Plus (K1204140 has three different coping types for the fabrication of screw-retained prostheses (prosthetic screw). Both prosthetic coping systems are for single or multi-unit restorations that are removable. Rodo Abutment System and Low Profile Abutment (K092341) are available with 17° and 30° angled abutments.

Rodo Abutment System abutments range in size from Ø 3.0 mm to Ø 6.0 mm. OsseoSpeed Plus Abutments range in size from Ø 3.0 mm to Ø 5.4 mm. Low Profile Abutments range in size from Ø 3.4 mm to Ø 5.0 mm.

The Indications for Use for the Rodo Abutment System are substantially equivalent to those of OsseoSpeed Plus and Low Profile Abutment. Minor differences in Indications for Use language between the systems do not change the intended use of support for prostheses in the maxillary or mandibular arch.

Below is a summary table comparing the Indications for Use and the technological characteristics of the subject device and the predicate devices.
Table of Substantial Equivalence

<table>
<thead>
<tr>
<th>Subject Device</th>
<th>Primary Predicate</th>
<th>Reference Predicate</th>
<th>Reference Predicate</th>
</tr>
</thead>
</table>
| Rodo Medical, Inc.  
Rodo Abutment System | Astra Tech AB  
OsseoSpeed® Plus | K160786 | Biomet 3i  
Low Profile Abutment | K120414 |
| K160786 | K092341 | K142118 |

### Indications for Use

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.

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### Design

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<th>Restoration</th>
<th>Abutment Platform Diameters</th>
<th>Abutment Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smileloc Sleeve (Nitinol alloy)</td>
<td>Single-unit, Multi-unit</td>
<td>3.0 mm - 6.0 mm</td>
<td>Titanium alloy</td>
</tr>
<tr>
<td>Screw-retained, Cement-retained</td>
<td>Single-unit, Multi-unit</td>
<td>3.0 mm - 5.4 mm</td>
<td>Titanium alloy</td>
</tr>
<tr>
<td>Screw Retained</td>
<td>Single-unit, Multi-unit</td>
<td>3.4 mm - 5.0 mm</td>
<td>Titanium alloy</td>
</tr>
<tr>
<td>Screw-retained</td>
<td>Single-unit, Multi-unit</td>
<td>3.3 - 4.8 mm</td>
<td>Titanium alloy</td>
</tr>
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</table>
CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter, gingival height, and angle of the abutments. The subject and predicate devices are packaged in similar materials and are to be sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.