DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 11, 2016

Rhein'83 SRL
Ms. Claudia Nardi
President Rhein'83 SRL
Via E. Zago 10/abc
Bologna, 40128
ITALY

Re: K160382
Trade/Device Name: OT EQUATOR
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 05, 2016
Received: July 11, 2016

Dear Ms. Nardi:

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,

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 below.

510(k) Number *(if known)*

K160382

Device Name
OT Equator

Indications for Use *(Describe)*

The OT Equator is designed as an endosseous dental implant retentive component used to retain a complete or partial denture. The OT Equator is screwed into an endosseous implant in the mandible or maxilla.
The OT Equator abutments are indicated for use with the following implant systems:
NOBEL BIOCARE AB - NobelActive NP 3.5
NOBEL BIOCARE AB - NobelActive RP 4,3 - 5
NOBEL BIOCARE USA LLC - Replace Select TC NP 3.5
NOBEL BIOCARE USA INC - Replace Select Straight TiUnit RP 4.3
NOBEL BIOCARE USA LLC - Replace Select Straight TiUnit WP 5
NOBEL BIOCARE AB - Brånemark System Mk III TiUnite NP 3.3
NOBEL BIOCARE AB - Brånemark System Mk III Shorty RP 4,1
NOBEL BIOCARE AB - Brånemark System Mk III TiUnite WP5 6
Straumann USA - Bone level NC 3.3
Straumann USA - Bone level RC 4.1 – 4.8
Straumann USA - Tissue level RN 4,8
Straumann USA - Tissue level WN 6,5
Zimmer Dental Inc. - Tapered Screw-Vent 3.5, 4.5, 5.7
Zimmer Dental Inc. - Spline 3.25, 3.75 - 4, 5
ASTRA TECH AB - OsseoSpeed™ TX 3.5-4, 4.5-5
DENTSPLY INTL., INC. - ANKYLOS C/ 3,5
DENTSPLY INTERNATIONAL, INC. - FRIALIT plus Stepped Screw 3.4, 3.8, 4.5, 5.5, 6.5
BIOMET 3i - Certain 3.25, 4.1, 5, 6
IMPLANT DIRECT LLC - Legacy 3, 3.75, 4.7
IMPLANT DIRECT LLC - Tri-Lobe 3.5, 4.3, 5 - 6
IMPLANT DIRECT LLC - Tri-Lobe 3.5, 4.3, 5 - 6
IMPLANT DIRECT SYBRON MANUFACTURING LLC - Swish Plus3.7, 4.1 – 4.8
MIS - IMPLANT TECHNOLOGIES LTD. - SEVEN 3.3, 3.75, 4.2, 5, 6
MIS - IMPLANT TECHNOLOGIES LTD. - C1 3.3, 3.75, 3.9, 4.2, 4.3, 5
MEGAGEN CO., LTD. - ANYRIDGE 3.5, 4, 4.5, 5, 5.5
NEODENT USA, INC. - CM Titamax 3.5, 3.75, 4, 4.3, 5
NEODENT USA, INC. - CM Drive 3.5, 3.75, 4, 4.3, 5
NEOSS, LTD. - ProActive 3.5, 4, 4.5, 5, 5.5, 6
BIOHORIZONS IMPLANT SYSTEMS, INC. - Laser-lok® 3.0
BIOHORIZONS IMPLANT SYSTEMS, INC. - Tapered internal 3.5, 4.5, 5.7
KEYSTONE DENTAL, INC. / LIFECORE BIOMEDICAL, INC - PRIMACONNEX INTERNAL CONNECTION IMPLANT SYSTEM SD 3.5
KEYSTONE DENTAL, INC. / LIFECORE BIOMEDICAL, INC - PRIMACONNEX INTERNAL CONNECTION IMPLANT SYSTEM RD 4.1
KEYSTONE DENTAL, INC. / LIFECORE BIOMEDICAL, INC - PRIMACONNEX INTERNAL CONNECTION IMPLANT SYSTEM WD 5

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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Section 05 - 510(k) Summary

Applicant:

Company Name: Rhein'83 srl
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Company Fax: +39 051245238
Company e-mail info@rhein83.com
Official Contact for Correspondence: Claudia Nardi – President Rhein'83 srl

Date Summary Prepared: July 11, 2016

DEVICE IDENTIFICATION

Trade name: OT EQUATOR
Generic/ Common Name: Implant Abutment
Classification : 21 CFR 872.3630
Classification name: ENDOSSEOUS DENTAL IMPLANT ABUTMENT
CLASS II (SPECIAL CONTROLS)
Product Code: NHA
Panel: Dental

Predicate Devices

Predicate : OT Equator (K142211)

DEVICE DESCRIPTION

The OT Equator Implant Anchor abutment for endosseous dental implants is appropriate for use with overdentures or partial denture retained in whole or in part by endosseous implants in the mandibula or maxilla. The device is intended for use in healthcare facilities/hospitals

The sphere OT Equator technology represents a prosthetic abutment solution for "overdenture". The emerging profile, specifically designed to accommodate the relative interchangeable copings OT Equator, allows the coupling with a removable prosthesis or "overdenture", which is properly built only if it is properly profiled and based on the patient's gingival arch. Therefore, the removable prosthesis unloads the chewer loads on the natural gum of the intra oral arch, making the OT Equator abutments passive with lacking of solicitation.

The OT Equator is manufactured of titanium Ti-6Al-4V (meets ASTM Standard F-136) and it is designed to retain any compatible prosthetic restoration.

The OT Equator overdenture system is comprised of a semispherical head, a base, and a screw.

The part number, critical dimensions and materials for the OT Equator Abutment and accessories subject to this 510(k) are summarized below:

Component name and drawing	Part Number	Critical Dimensions	Material
OT EQUATOR ABUTMENT 	030	HEAD DIAMETER: 2.5mm HEAD HEIGHT: 2.0 MM CUFF HEIGHT: From 1 to 7mm THREAD DIAMETER: Congruent with implant Threaded CONNETIONS: Different implant platforms	TITANIUM Medical Grade 5 E.L.I. (Ti6AL4V) Surface treatment: TiN coating (Nitride) ONLY IN THE HEAD OF THE ABUTMENT
OT EQUATOR – VIOLET RETENTIVE CAP 	140CEV	EXTERNAL Ø 3.8mm INTERNAL Ø 2.5mm	KEPITAL
OT EQUATOR – WHITE RETENTIVE CAP 	140CET	EXTERNAL Ø 3.8mm INTERNAL Ø 2.5mm	RILSAN BMNO
OT EQUATOR – PINK RETENTIVE CAP 	140CER	EXTERNAL Ø 3.8mm INTERNAL Ø 2.5mm	RILSAN BMNO

Component name and drawing	Part Number	Critical Dimensions	Material
OT EQUATOR – YELLOW RETENTIVE CAP 	140CEG	EXTERNAL Ø 3.8mm INTERNAL Ø 2.5mm	PEBAX
OT EQUATOR HOUSING FOR CAP 	141CAE	INTERNAL Ø 3.84	STAINLESS STEEL AISI303

INTENDED USE /INDICATIONS FOR USE

The OT Equator is designed as an endosseous dental implant retentive component used to retain a complete or partial denture. The OT Equator is screwed into an endosseous implant in the mandible or maxilla.

The OT Equator abutments are indicated for use with the following implant systems:
NOBEL BIOCARE AB - NobelActive NP 3.5
NOBEL BIOCARE AB - NobelActive RP 4,3 - 5
NOBEL BIOCARE USA LLC - Replace Select TC NP 3.5
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NOBEL BIOCARE AB - Brånemark System Mk III TiUnite NP 3.3
NOBEL BIOCARE AB - Brånemark System Mk III Shorty RP 4,1
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DENTSPLY INTERNATIONAL, INC. - FRIALIT plus Stepped Screw 3.4, 3.8, 4.5, 5.5, 6.5
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IMPLANT DIRECT SYBRON MANUFACTURING LLC - Swish Plus3.7, 4.1 – 4.8
MIS - IMPLANT TECHNOLOGIES LTD. - SEVEN 3.3, 3.75, 4.2, 5, 6

MIS - IMPLANT TECHNOLOGIES LTD. - C1 3.3, 3.75, 3.9, 4.2, 4.3, 5
MEGAGEN CO., LTD. - ANYRIDGE 3.5, 4, 4.5, 5, 5.5
NEODENT USA, INC. - CM Titamax 3.5, 3.75, 4, 4.3, 5
NEODENT USA, INC. - CM Drive 3.5, 3.75, 4, 4.3, 5
NEOSS, LTD. - ProActive 3.5, 4, 4.5, 5, 5.5, 6
BIOHORIZONS IMPLANT SYSTEMS, INC. - Laser-lok® 3.0
BIOHORIZONS IMPLANT SYSTEMS, INC. - Tapered internal 3.5, 4.5, 5.7
KEYSTONE DENTAL, INC. / LIFECORE BIOMEDICAL, INC - PRIMACONNEX INTERNAL CONNECTION IMPLANT SYSTEM SD 3.5
KEYSTONE DENTAL, INC. / LIFECORE BIOMEDICAL, INC - PRIMACONNEX INTERNAL CONNECTION IMPLANT SYSTEM RD 4.1
KEYSTONE DENTAL, INC. / LIFECORE BIOMEDICAL, INC - PRIMACONNEX INTERNAL CONNECTION IMPLANT SYSTEM WD 5

DISCUSSION OF NON CLINICAL TESTS

Biocompatibility

The submitted device, as the predicate device, is classified as permanent duration (> 30 days), mucosal membranes contacting device.
The materials of the submitted device are identical to the ones of the predicate, the already licensed OT EQUATOR (K142211). All materials, including the coating for the OT EQUATOR Abutment, TiN (Nitride), are identical to the materials used to manufacture the predicate OT EQUATOR and its components (all cleared with 510(K) n. K142211). All the components are manufactured using the same process. Therefore, the results of the biocompatibility tests performed on the predicate device OT Equator apply also to the subject device and there was no need to perform new biocompatibility testing on the subject device OT EQUATOR.

Sterilization Validation

Steam sterilization validation test, conducted on the predicate device OT Equator according to ISO 17664 and ISO 11737-1/-2 in order to demonstrate as SAL of 10-6 related to the OT Equator abutments, are considered still valid, since the materials and packing of the subject device are the same of the predicate.

Reverse engineering analysis

In order to ensure that the OT Equator abutment can be perfectly coupled with the related compatible implant a reverse engineering analysis was conducted, as for the predicate already licensed. The implant dimension were detected with a stereo microscope and with a wide range of calibrated plugs. The exact dimensions of the threaded holes and the related tolerance degree were detected with the "go/no go" threaded gauges. In the same way the maximum depth of the threaded hole was detected with the related threaded gauge, with the aid of the profile projector.
The tests were conducted on a statistically significant number of OEM implant systems, and the results were reported in a chart form.
The results of nonclinical tests demonstrate that the device is substantially equivalent to the predicate device.

SUBSTANTIAL EQUIVALENCE

The OT EQUATOR is same or similar in materials, design and intended use to the predicate devices. In further support of a substantial equivalence determination, hereunder is a comparison chart with the submitted device and the predicate devices.

Feature	**Rhein'83 OT Equator (Submitted Product)**	**LEGALLY MARKETED PREDICATE DEVICE**
K number	K160382	K142211
Proprietary / Trade Name	OT EQUATOR	OT EQUATOR
CFR Section	872.3630	872.3630
Pro-code	NHA	NHA
Classification name	ENDOSSEOUS DENTAL IMPLANT ABUTMENT Class II (special controls)	ENDOSSEOUS DENTAL IMPLANT ABUTMENT Class II (special controls)
Indications For Use / Intended Use	The OT Equator is designed as an endosseous dental implant retentive component used to retain a complete or partial denture. The OT Equator is screwed into an endosseous implant in the mandible or maxilla.	The OT Equator is designed as an endosseous dental implant retentive component used to retain a complete or partial denture. The OT Equator is screwed into an endosseous implant in the mandible or maxilla.
Intended Users	Adequately trained dental technicians and dentists.	Adequately trained dental technicians and dentists.
Material	Titanium 6Al-4V	Titanium 6Al-4V
Material (Male socket)	Rilsan, Pebax, Kepital	Rilsan, Pebax, Kepital

Feature	Rhein'83 OT Equator (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICE
K number	K160382	K142211
Material (Housing)	Stainless Steel AISI303	Stainless Steel AISI303
Platform Diameter	According to the compatible implant (see table above, indication for use)	According to the compatible implant (see table above, indication for use)
Surface treatment	TiN coating only for the head part of the abutment	TiN coating only for the head part of the abutment
Cuff Width	1mm – 2mm - 3mm – 4mm – 5mm – 6mm- 7mm	1mm – 2mm - 3mm – 4mm 5mm – 6mm- 7mm
Height	2 mm	2 mm
Components	OT EQUATOR PROFILE kit contains: Ot Equator Profile abutment, metal housing, retentive caps, protective disk.	OT EQUATOR PROFILE kit contains: Ot Equator Profile abutment, metal housing, retentive caps, protective disk.
Sterilization	Marketed non sterile, to be sterilized before insertion in patient's mouth.	Marketed non sterile, to be sterilized before insertion in patient's mouth.
Reusable	No	No

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed device and the predicate OT EQUATOR already licensed (K142211) are identical in all specifications as the materials, the manufacturing process, the technological characteristics and the indications for use except for the interface connections between the abutments and the compatible implant bodies,that have specific dimensions, according to the compatible implant systems.

The subject device varies from the predicate already licensed only for the list of compatible implant systems.

CONCLUSIONS

Based on the available information, we conclude that the OT Equator is substantially equivalent to the existing legally marketed device under Federal Food, Drug and Cosmetic Act. Therefore, the subject device is determined to be substantially equivalent to the predicate device.