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

November 25, 2015

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

Re: K142211
Trade/Device Name: OT EQUATOR
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 19, 2015
Received: October 26, 2015

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,

Erin I. Keith -S

Erin I. Keith, M.S.
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.*

51O(k) Number *(if known)*
KI42211

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 implant systems listed in Attachment B.

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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"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."*

Attachment B - IFU table - FORM FDA 3881 – K142211 - OT Equator

Manufacturer	Implant Family Name	Implant Name	Implant Diameter
NOBEL BIOCARE AB	NobelActive	NobelActive NP	3.5
		NobelActive RP	4,3 - 5
NOBEL BIOCARE USA LLC	Nobelreplace Tapered Conical Connection	Replace Select TC NP	3.5
NOBEL BIOCARE USA INC	Replace Tiunite Endosseous Implant	Replace Select Straight TiUnit RP	4.3
NOBEL BIOCARE USA LLC	Replace Tiunite Endosseous Implant	Replace Select Straight TiUnit WP	5
NOBEL BIOCARE AB	Various Branemark System Implants-Immediate Function Indication	Brånemark System Mk III TiUnite NP	3.3
		Brånemark System Mk III Shorty RP	4,1
		Brånemark System Mk III TiUnite WP	5 6
Straumann USA	Straumann Bone Level Tapered Implant	Bone level NC	3.3
		Bone level RC	4.1 – 4.8
	ITI Dental Implant System (Tissue Level Titanium Implants)	Tissue level RN	4,8
		Tissue level WN	6,5
Zimmer Dental Inc.	Tapered Screw-Vent Implant System	Tapered Screw-Vent	3.5 4.5 5.7
	Spline Dental Implant System	Spline	3.25 3.75 - 4 5
ASTRA TECH AB	Astra Tech Implant System	OsseoSpeed™ TX	3.5-4 4.5-5
DENTSPLY INTL., INC.	ANKYLOS C/X DENTAL IMPLANT SYSTEM	ANKYLOS C/	3,5
DENTSPLY INTERNATIONAL, INC.	Frialit Plus, Xive S Plus, Xive Tg Plus, Ankylos Plus, Dental Implant Systems	FRIALIT plus Stepped Screw	3.4 3.8 4.5 5.5 6.5
BIOMET 3i	Full OSSEOTITE® Certain® II Dental Implant	Certain	3.25 4.1 5 6
IMPLANT DIRECT LLC	Legacy Dental Implants	Legacy	3 3.75 4.7
	Reactive Dental Implant System	Tri-Lobe	3.5 4.3 5 - 6
	Replus Dental Implants	Tri-Lobe	3.5 4.3 5 - 6
IMPLANT DIRECT SYBRON MANUFACTURING LLC	Interactive/ Swishplus2 Implant System	Swish Plus	3,7 4,1 – 4,8

Section 05 - 510(k) Summary

Applicant:
Company Name: Rhein'83 srl
Company Address: via E. Zago 10/abc - 40128 Bologna - Italy
Company Phone: +39 051244510
Company Fax: +39 051245238
Company e-mail info@rhein83.com
Official Contact for Correspondence: Claudia Nardi – President Rhein'83 srl

Date Summary Prepared: October 19, 2015

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
Primary Predicate :
-Sphero Flex, Sphero Block, Pivot Flex (K033630)

Reference Predicates:
- Quick Coupling For Dental Prostheses (K950260)
-Device For Providing Quick Coupling For Dental Prostheses (K950260)

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 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 prosthetic restoration.

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

The proposed device and the predicates SPHERO FLEX and SPHERO BLOCK (K950260 - K950261 - K033630) are equivalent in some specifications (the dimensions of the head between the predicate Sphero-Block and OT Equator differ slightly), and identical in other specifications as the interface connections between the abutments and the implant body, the materials, the manufacturing process, the technological characteristics and the Indications for Use.

The Titanium abutment has one side with a thread to secure the connection to a dental implant. On the other side there is a hemisphere that must be connected to the prosthesis.

The OT Equator varies from the predicate Sphero Block as follows: on the Sphero block the complete round sphere inclusive of the hexagon base is 3.4mm in height; the OT Equator does not contain a complete round sphere or a hexagon base, and it is 2mm in height. The diameter of the Sphero Block sphere and the OT Equator half-sphere is the same of 2.5 mm, they vary only in height.

The anchoring of the prosthesis to the attachments is ensured by the coupling precision between the retentive cap inserted in a steel housing and the spherical section of the upper part of the abutments. In order to enable this connection the following components have been made:

The METAL HOUSING is a stainless steel prefabricated device with proper internal dimensions able to host the OT EQUATOR retentive cap in order to secure a coupling between abutment/retentive cap as precise as possible.

The metal housing must be placed into the prosthesis, then a RETENTIVE CAP must be inserted into the metal housing, then the prosthesis must press on the abutments for the connection of the denture.

Retention caps are elastic elements that allow the union between the steel housing and the abutment by regulating the retention strength in a prosthetic project. The special internal design of the cap allows embracing the attachment’s ball when it is snapped into the cap .

The retention caps are manufactured in different materials that give to the product different retention strength. They are also made in different color in order to permit to selection of the elastic properties of the material of which they are composed. The different colors allow distinguishing the different retention strength.

The subject device is provided with a threaded stem to be screwed into a dental implant. This component is coated with TiN in the upper part, where it must be connected with Retentive caps.

The OT Equator and the predicate Sphero-Block are identical in every way (materials, additives, manufacturing process and intended use) except the dimensions, in that the dimension of the head of the OT Equator is not a complete sphere but semi-sphere. The verbiage of the Indications for Use Statement for the subject abutment has been modified to add new compatible implant fixtures has compared to the predicate; however the new compatibility does not change the intended use as compared to the declared predicate.
The other components listed below are also different only in size (they must fit with the semi-sphere and a complete sphere). The tools are the same as used with the Sphero-Block.

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 	130	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

The only device and components for which clearance is requested in this 510(k) are identified above. All other components not identified below were cleared in the predicate Sphero-Block 510(k) submission.

The OT EQUATOR abutments are provided straight and do not contain any inherent angulation to provide an angle correction.

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 implant systems listed in the Table below:

Manufacturer	**Implant Family Name**	**Implant Name**	**Implant Diameter**
NOBEL BIOCARE AB	NobelActive	NobelActive NP	3.5
		NobelActive RP	4,3 - 5
NOBEL BIOCARE USA LLC	Nobelreplace Tapered Conical Connection	Replace Select TC NP	3.5
NOBEL BIOCARE USA INC	Replace Tiunite Endosseous Implant	Replace Select Straight TiUnit RP	4.3
NOBEL BIOCARE USA LLC	Replace Tiunite Endosseous Implant	Replace Select Straight TiUnit WP	5
NOBEL BIOCARE AB	Various Branemark System Implants-Immediate Function Indication	Brånemark System Mk III TiUnite NP	3.3
		Brånemark System Mk III Shorty RP	4,1

Manufacturer	Implant Family Name	Implant Name	Implant Diameter
		Brånemark System Mk III TiUnite WP	5 6
Straumann USA	Straumann Bone Level Tapered Implant	Bone level NC	3.3
		Bone level RC	4.1 – 4.8
	ITI Dental Implant System (Tissue Level Titanium Implants)	Tissue level RN	4,8
		Tissue level WN	6,5
Zimmer Dental Inc.	Tapered Screw-Vent Implant System	Tapered Screw-Vent	3.5 4.5 5.7
	Spline Dental Implant System	Spline	3.25 3.75 - 4 5
ASTRA TECH AB	Astra Tech Implant System	OsseoSpeed™ TX	3.5-4 4.5-5
DENTSPLY INTL., INC.	ANKYLOS C/X DENTAL IMPLANT SYSTEM	ANKYLOS C/	3,5
DENTSPLY INTERNATIONAL, INC.	Frialit Plus, Xive S Plus, Xive Tg Plus, Ankylos Plus, Dental Implant Systems	FRIALIT plus Stepped Screw	3.4 3.8 4.5 5.5 6.5
BIOMET 3i	Full OSSEOTITE® Certain® II Dental Implant	Certain	3.25 4.1 5 6
IMPLANT DIRECT LLC	Legacy Dental Implants	Legacy	3 3.75 4.7
	Reactive Dental Implant System	Tri-Lobe	3.5 4.3 5 - 6
	Replus Dental Implants	Tri-Lobe	3.5 4.3 5 - 6
IMPLANT DIRECT SYBRON MANUFACTURING LLC	Interactive/ Swishplus2 Implant System	Swish Plus	3,7 4,1 – 4,8

DISCUSSION OF NON CLINICAL TESTS

Biocompatibility

The materials are identical to the predicate, the Sphero-Block (K033630). All materials, including the coating for the OT EQUATOR Abutment, TiN (Nitride), are identical to the Sphero-Block and

components cleared in the predicate 510(k). Therefore, no biocompatibility testing was conducted for the subject OT EQUATOR based on the materials being identical to the predicate, conformance to an FDA recognized standard (i.e. ASTM F136), and all components being manufactured using the same process. No additional biocompatibility testing is needed for the determination of substantial equivalence.

Mechanical strength

In order to verify whether the final strength of the product meets the design requirements the mechanical strength was analyzed according both to FDA Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments, 2004 and ISO 14801 standard, Dentistry- implants- dynamic Fatigue Test For Endosseous Dental Implants.

Compression tests (static and dynamic) were run to check the various connections for adequate strength. The test results demonstrate that the products demonstrate substantial equivalence performance to the declared predicate devices.

Fatigue

Fatigue tests were performed according to ISO 14801 on the OT Equator models. Also for this test the smallest compatible implant was chosen as worst case. Test results provide evidence that OT Equator demonstrates substantial equivalence performance as compared to the declared predicate devices.

Sterilization Validation

Steam sterilization validation test was conducted according to ISO 17664 and ISO 11737-1/-2 in order to demonstrate as SAL of 10-6 related to the OT Equator abutments.

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,

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.

Information provided, in the reverse engineering analysis report included identification of features critical to fit, dimensions, tolerances, and cross-sections CAD images showing the assembled devices, dimensions, and interface gaps. The analysis demonstrated the compatibility of the subject abutment to the identified dental implant body.

The results of nonclinical tests demonstrate that the device is 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	Rhein83 OT Equator (Submitted Product)	LEGALLY MARKETED PREDICATE DEVICES OF
K number	n.a.	K950260 K950261 K033630
Proprietary / Trade Name	OT EQUATOR	SPHERO FLEX-SPHERO BLOCK
CFR Section	872.3630	872.3640
Pro-code	NHA	DZE
Classification name	Endosseous dental implant Abutment Class II (special controls)	Endosseous dental implant
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 Sphero Block Implant Anchors abutments for endosseous dentam implants are appropriate for use with overdentures or partial retained in whole or in part by endosseous implants in the mandibular 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
Platform Diameter	According to the compatible implant	According to the compatible implant
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	2.8 mm – 3.4 mm
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

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