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

April 9, 2018

Re: K171409
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: March 6, 2018
Received: March 8, 2018

Dear Claudia 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.

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

forTina 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K 171409

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:

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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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Implant Manufacturer	Implant Family Name	Implant Name	Implant Diameter (mm)
NOBEL BIOCARE AB	NobelActive	NobelActive NP	3.5
NOBEL BIOCARE AB	NobelActive	NobelActive RP	4.3 and 5
NOBEL BIOCARE USA LLC	Nobelreplace Tapered Conical Connection	Replace Select TC NP	3.5
NOBEL BIOCARE UAS INC	Replace Tiunite Endosseous Implant	Replace Select Straight TiUnit RP	4.3
NOBEL BIOCARE UAS INC	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
NOBEL BIOCARE AB	Various Branemark System Implants-Immediate Function Indication	Brånemark System Mk III Shorty RP	4.1
NOBEL BIOCARE AB	Various Branemark System Implants-Immediate Function Indication	Brånemark System Mk III TiUnite WP	5 and 6
STRAUMANN USA	Straumann Bone Level Tapered Implant	Bone level NC	3.3
STRAUMANN USA	Straumann Bone Level Tapered Implant	Bone level RC	4.1 and 4.8
STRAUMANN USA	ITI Dental Implant System (Tissue Level Titanium Implants)	Tissue level RN	4.8
STRAUMANN USA	ITI Dental Implant System (Tissue Level Titanium Implants)	Tissue level WN	6.5
ZIMMER DENTAL INC.	Tapered Screw-Vent Implant System	Tapered Screw-Vent	3.5, 4.5 and 5.7
ZIMMER DENTAL INC	Spline Dental Implant System	Spline	3.25 , 3.75 , 4 and 5
ASTRA TECH AB	Astra Tech Implant System	OsseoSpeed™ TX	3.5 , 4 , 4.5 and 5
DENTSPLY INTERNATIONAL, 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 and 6.5
BIOMET 3i	Full OSSEOTITE® Certain® II Dental Implant	Certain	3.25 , 4.1 , 5 and 6

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Implant Manufacturer	Implant Family Name	Implant Name	Implant Diameter (mm)
IMPLANT DIRECT LLC	Legacy Dental Implants	Legacy	3 , 3.75 and 4.7
IMPLANT DIRECT LLC	Reactive Dental Implant System	Tri-Lobe	3.5 , 4.3 , 5 and 6
IMPLANT DIRECT LLC	Replus Dental Implants	Tri-Lobe	3.5 , 4.3 , 5 and 6
IMPLANT DIRECT SYBRON MANUFACTURING LLC	Interactive/ Swishplus2 Implant System	Swish Plus	3.7 , 4.1 and 4.8
NEODENT USA, INC.	Neodent Implant System	CM Titamax	3.5 , 3.75 , 4 , 4.3 and 5
NEODENT USA, INC.	Neodent Implant System	CM Drive	3.5 , 3.75 , 4 , 4.3 and 5
MIS - IMPLANT TECHNOLOGIES LTD.	Seven Implants; Biocom Implants; Lance Implants	Seven	3.3 , 3.75 , 4.2 , 5 and 6
MIS - IMPLANT TECHNOLOGIES LTD.	Conical Connection Implants	C1	3.3 , 3.75 , 3.9 , 4.2 , 4.3 and 5
MEGAGEN CO., LTD.	Anyridge Internal Implant System	Anyridge	3.5 , 4 , 4.5 , 5 and 5.5
NEOSS, LTD.	Neoss Proactive Implant	ProActive	3.5 , 4 , 4.5 , 5 , 5.5 and 6
BIOHORIZONS IMPLANT SYSTEMS, INC.	Biohorizons Laser-Lok 3.0 Implant System	Laser-lok®	3.0
BIOHORIZONS IMPLANT SYSTEMS, INC.	Biohorizons Tapered Internal Implant System	Tapered internal	3.5 , 4.5 and 5.7
KEYSTONE DENTAL INC. / LIFECORE BIOMEDICAL INC	Primaconnex Internal Connection Implant System, Primaconnex Internal Connection Prosthetics	Primaconnex Internal Connection Implant System SD	3.5
KEYSTONE DENTAL INC. / LIFECORE BIOMEDICAL INC	Primaconnex Internal Connection Implant System, Primaconnex Internal Connection Prosthetics	Primaconnex Internal Connection Implant System RD	4.1
KEYSTONE DENTAL INC. / LIFECORE BIOMEDICAL INC	Primaconnex Internal Connection Implant System, Primaconnex Internal Connection Prosthetics	Primaconnex Internal Connection Implant System WD	5
TRI DENTAL IMPLANTS INT. AG	TRI® Dental Implant System	TRI Narrow	3.3
TRI DENTAL IMPLANTS INT. AG	TRI® Dental Implant System	TRI Vent	3.75 , 4.1 and 4.7
TRI DENTAL IMPLANTS INT. AG	TRI® Dental Implant System	TRI OCTA	3.75 , 4.1 and 4.7

Implant Manufacturer	Implant Family Name	Implant Name	Implant Diameter (mm)
ALTATEC GMBH	Camlog Implant System Modified Implants and Abutments	Camlog	3.3 , 3.8 , 4.3 , 5 and 6
ALTATEC GMBH	Conelog Implant System	Conelog	3.3 , 3.8 , 4.3 and 5
DENTIS CO.	Dentis Dental Implant System	i-Clean	3.7 , 4.3 and 4.8
DENTIS CO.	OneQ-SL Implant System Common	i-Clean	3.7 , 4.3 and 4.8
DENTIS CO.	OneQ-SL s-Clean Implant System s-Clean Tapered II RBM Implant System	s-clean	3.7 , 4.3 and 4.8
DENTIS CO.	Dentis Dental Implant System	e-Clean	3.5 , 4.1 and 5.1
DENTSPLY IMPLANTS MANUFACTURING GMBH	Astra Tech Implant System	OsseoSpeed Profile EV	3 , 3.6 , 4.2 and 4.8
MEGAGEN IMPLANT CO.	Anyone Internal Implant System	Anyone	3.6 , 4.0 , 4.5 , 5 and 6

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
Phone:	+39 051244510
E-mail:	info@rhein83.com

Date Summary Prepared: April 4, 2018

DEVICE IDENTIFICATION

Trade name:	OT EQUATOR
Generic/ Common Name:	Implant Abutment
Classification:	21 CFR 872.3630
Classification name:	Endosseous dental implant Abutment Class II
Product Code:	NHA
Panel:	Dental

PREDICATE DEVICES:

Primary predicate: K142211, OT Equator, Rhein'83 srl

Reference device: K160382, OT Equator, Rhein'83 srl

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 abutments are for straight use only and are recommended for placement on straight implant bodies with no divergence or need for angle corrections.

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 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 CONNECTIONS: 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
OT EQUATOR – YELLOW RETENTIVE CAP 	140CEG	EXTERNAL Ø 3.8mm INTERNAL Ø 2.5mm	PEBAX

Component name and drawing	Part Number	Critical Dimensions	Material
STAINLESS STEEL 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:

Implant Manufacturer	Implant Family Name	Implant Name	Implant Diameter (mm)
NOBEL BIOCARE AB	NobelActive	NobelActive NP	3.5
NOBEL BIOCARE AB	NobelActive	NobelActive RP	4.3 and 5
NOBEL BIOCARE USA LLC	Nobelreplace Tapered Conical Connection	Replace Select TC NP	3.5
NOBEL BIOCARE UAS INC	Replace Tiunite Endosseous Implant	Replace Select Straight TiUnit RP	4.3
NOBEL BIOCARE UAS INC	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
NOBEL BIOCARE AB	Various Branemark System Implants-Immediate Function Indication	Brånemark System Mk III Shorty RP	4.1
NOBEL BIOCARE AB	Various Branemark System Implants-Immediate Function Indication	Brånemark System Mk III TiUnite WP	5 and 6
STRAUMANN USA	Straumann Bone Level Tapered Implant	Bone level NC	3.3
STRAUMANN USA	Straumann Bone Level Tapered Implant	Bone level RC	4.1 and 4.8
STRAUMANN USA	ITI Dental Implant System (Tissue Level Titanium Implants)	Tissue level RN	4.8
STRAUMANN USA	ITI Dental Implant System (Tissue Level Titanium Implants)	Tissue level WN	6.5
ZIMMER DENTAL INC.	Tapered Screw-Vent Implant System	Tapered Screw-Vent	3.5, 4.5 and 5.7
ZIMMER DENTAL INC	Spline Dental Implant System	Spline	3.25 , 3.75 , 4 and 5

ASTRA TECH AB	Astra Tech Implant System	OsseoSpeed™ TX	3.5 , 4 , 4.5 and 5
DENTSPLY INTERNATIONAL, 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 and 6.5
BIOMET 3i	Full OSSEOTITE® Certain® II Dental Implant	Certain	3.25 , 4.1 , 5 and 6
IMPLANT DIRECT LLC	Legacy Dental Implants	Legacy	3 , 3.75 and 4.7
IMPLANT DIRECT LLC	Reactive Dental Implant System	Tri-Lobe	3.5 , 4.3 , 5 and 6
IMPLANT DIRECT LLC	Replus Dental Implants	Tri-Lobe	3.5 , 4.3 , 5 and 6
IMPLANT DIRECT SYBRON MANUFACTURING LLC	Interactive/ Swishplus2 Implant System	Swish Plus	3.7 , 4.1 and 4.8
NEODENT USA, INC.	Neodent Implant System	CM Titamax	3.5 , 3.75 , 4 , 4.3 and 5
NEODENT USA, INC.	Neodent Implant System	CM Drive	3.5 , 3.75 , 4 , 4.3 and 5
MIS - IMPLANT TECHNOLOGIES LTD.	Seven Implants; Biocom Implants; Lance Implants	Seven	3.3 , 3.75 , 4.2 , 5 and 6
MIS - IMPLANT TECHNOLOGIES LTD.	Conical Connection Implants	C1	3.3 , 3.75 , 3.9 , 4.2 , 4.3 and 5
MEGAGEN CO., LTD.	Anyridge Internal Implant System	Anyridge	3.5 , 4 , 4.5 , 5 and 5.5
NEOSS, LTD.	Neoss Proactive Implant	ProActive	3.5 , 4 , 4.5 , 5 , 5.5 and 6
BIOHORIZONS IMPLANT SYSTEMS, INC.	Biohorizons Laser-Lok 3.0 Implant System	Laser-lok®	3.0
BIOHORIZONS IMPLANT SYSTEMS, INC.	Biohorizons Tapered Internal Implant System	Tapered internal	3.5 , 4.5 and 5.7
KEYSTONE DENTAL INC. / LIFECORE BIOMEDICAL INC	Primaconnex Internal Connection Implant System, Primaconnex Internal Connection Prosthetics	Primaconnex Internal Connection Implant System SD	3.5
KEYSTONE DENTAL INC. / LIFECORE BIOMEDICAL INC	Primaconnex Internal Connection Implant System, Primaconnex Internal Connection Prosthetics	Primaconnex Internal Connection Implant System RD	4.1
KEYSTONE DENTAL INC. / LIFECORE BIOMEDICAL INC	Primaconnex Internal Connection Implant System, Primaconnex Internal Connection Prosthetics	Primaconnex Internal Connection Implant System WD	5
TRI DENTAL IMPLANTS INT. AG	TRI® Dental Implant System	TRI Narrow	3.3
TRI DENTAL IMPLANTS INT. AG	TRI® Dental Implant System	TRI Vent	3.75 , 4.1 and 4.7
TRI DENTAL IMPLANTS INT. AG	TRI® Dental Implant System	TRI OCTA	3.75 , 4.1 and 4.7
ALTATEC GMBH	Camlog Implant System Modified Implants and Abutments	Camlog	3.3 , 3.8 , 4.3 , 5 and 6
ALTATEC GMBH	Conelog Implant System	Conelog	3.3 , 3.8 , 4.3 and 5

DENTIS CO.	Dentis Dental Implant System	i-Clean	3.7 , 4.3 and 4.8
DENTIS CO.	OneQ-SL Implant System Common	i-Clean	3.7 , 4.3 and 4.8
DENTIS CO.	OneQ-SL s-Clean Implant System s-Clean Tapered II RBM Implant System	s-clean	3.7 , 4.3 and 4.8
DENTIS CO.	Dentis Dental Implant System	e-Clean	3.5 , 4.1 and 5.1
DENTSPLY IMPLANTS MANUFACTURING GMBH	Astra Tech Implant System	OsseoSpeed Profile EV	3 , 3.6 , 4.2 and 4.8
MEGAGEN IMPLANT CO.	Anyone Internal Implant System	Anyone	3.6 , 4.0 , 4.5 , 5 and 6

DISCUSSION OF NON CLINICAL TESTS

Biocompatibility

The submitted device, as the predicate devices already licensed (OT EQUATOR K142211 and K160382), is classified as permanent duration (> 30 days), mucosal membranes contacting device. The materials used to manufacture the submitted device are identical to the materials used for the identified predicate devices, the already licensed OT EQUATOR (K142211 and K160382). The materials used to manufacture the submitted device are identical to the materials used for the identified predicate devices and the same process is performed, including the TiN (Titanium Nitride) coating for the OT EQUATOR abutment; the modified surface of the abutment after the coating process is identical to the surface of the predicate devices. The type and duration of patient contact are the same as well.

Therefore, the results of the biocompatibility tests performed on the predicate devices OT EQUATOR apply also to the subject device and there was no need to perform new biocompatibility testing on the subject device OT EQUATOR. No additional biocompatibility testing is needed for the determination of substantial equivalence.

Sterilization Validation

Steam sterilization validation test, conducted on the predicate device OT EQUATOR (K142211) 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 coupled with the related compatible implant a reverse engineering analysis was conducted on the submitted device, as for the predicate devices already licensed; 10 samples of OEM implant system were used in the reverse engineering analysis: 10 OEM implant bodies and 10 OEM screws were reversed engineered, as for the predicate and reference devices, and the results were reported in a chart form.

The implant dimensions were detected with a stereo microscope and with a wide range of calibrated plugs. The 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 results of nonclinical tests demonstrate that the device is equivalent to the predicate devices.

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)	PREDICATE DEVICE	REFERENCE DEVICE
K number	N.A.	K160382	K142211
Proprietary / Trade Name	OT EQUATOR	OT EQUATOR	OT EQUATOR
CFR Section	872.3630	872.3630	872.3630
Pro-code	NHA	NHA	NHA
Classification name	ENDOSSEOUS DENTAL IMPLANT ABUTMENT Class II (special controls)	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. (contains a list of compatible implant bodies)	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. (contains a list of compatible implant bodies)	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. (contains a list of compatible implant bodies)
Intended Users	Adequately trained dental technicians and dentists.	Adequately trained dental technicians and dentists.	Adequately trained dental technicians and dentists.
Material	Titanium 6Al-4V	Titanium 6Al-4V	Titanium 6Al-4V
Material (Male socket)	Rilsan, Pebax, Kepital	Rilsan, Pebax, Kepital	Rilsan, Pebax, Kepital
Material (Housing)	Stainless Steel AISI303	Stainless Steel AISI303	Stainless Steel AISI303
Platform Diameter	According to the compatible implant (see table above)	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	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	1mm – 2mm – 3mm – 4mm –5mm – 6mm – 7mm
Height	2 mm	2 mm	2 mm
Components	OT EQUATOR PROFILE kit contains: Ot Equator Profile abutment, Stainless Steel Housing, retentive caps, protective disk.	OT EQUATOR PROFILE kit contains: Ot Equator Profile abutment, stainless steel housing , retentive caps, protective disk.	OT EQUATOR PROFILE kit contains: Ot Equator Profile abutment, stainless steel 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.	Marketed non sterile, to be sterilized before insertion in patient's mouth.
Reusable	No	No	No

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE DISCUSSION:

The Indications for Use Statements shown above in the comparison chart also contains a list of compatible implant bodies. The differences between the Indications for Use of the subject device and the primary predicate device is the addition of compatible implant bodies (Tri Dental Implants Int. AG, Altatec GMBH, Dentis Co., Dentsply Implants Manufacturing GMBH and Megagen Implant Co.).

As shown in the table above, the submitted device is substantial equivalent in all features: indications for use and intended users, materials, manufacturing process, cuff width, height, sterility status, components.

The subject device varies from the predicate devices only for the list of compatible implant systems, thus the only difference is in the interface connections between the abutments and the compatible implant bodies, that have specific dimensions according to the compatible implant systems. As for the predicate devices, in order to ensure that the OT Equator abutment can be coupled with the related compatible implant a reverse engineering analysis was conducted on the submitted device.
There are no additional differences, thus it was concluded that the subject dental implant abutment is substantially equivalent to the predicate devices.

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 equivalent to the predicate devices.