K122295

core 3d centres

Section 5 – 510(k) Summary

DATE OF SUBMISSION: 2013-10-16
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OCT 2 4 2013

DEVICE TRADE NAME: Core 3D Abutment System for Digital Prosthetic Solutions
COMMON NAME: Endosseous Dental Implant Abutment
CLASSIFICATION NAME: Endosseous Dental Implant Abutment (21 CFR 872.3630)

PREDICATE DEVICE(S): NT-Trading (K111935)
Biohorizons (K103291) Laser Lok for Nobel Biocare
Inclusive Dental Solutions (K083192)
3M Lava Software (K062493)

DEVICE DESCRIPTION:
The proposed devices are dental implant abutments intended to be placed into dental implants and to provide support for dental prosthetic restorations.

The system is composed of the following principal components:

- Titanium Bases to be attached to the underlying implant and upon which a CAD/CAM designed superstructure may be fitted to complete a two-piece dental abutment;
- Titanium Abutment Blanks with a pre-machined implant connection where the upper portion may be custom-milled in accordance with a patient-specific design using CAD/CAM techniques
- Abutment Screws: to fix abutments to the underlying dental implant.

The final form of the device including superstructures to be attached to titanium bases and patient-specific designs for abutment blanks may be designed using CAD CAM techniques under Core3D design specifications and limitations using the following system:

- CAD/CAM Software: 3Shape Dental System including 3Shape Dental Designer
- Scanner: 3Shape D810 model
- Milling machine: SAUER HSC-20 DMG.

Mechanical resistance of the implant-abutment connection is essential to ensure correct long-term functional performance of the complete dental restoration. Dimensional compatibility and mechanical performance of bases and screws together with the underlying implant are of primary importance. These concepts are the basis upon which the system design characteristics and functional

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performance are established.

The proposed Titanium Bases and Titanium Abutment Blanks are available with either an internal conical connection or external connection, depending on the underlying dental implant. The internal conical types are available in diameters of 3.4, 4.5, and 5.7mm for bases and in diameters of 3.5, 4.5 and 5.7mm for blanks. The external connection types are available in diameters of 3.5, 4.1 and 5.1mm. The available range of diameters and connection types are summarized below:

	Connection Type	Range of diameters
Abutment Bases	External Hex	3.5, 4.1, 5.1 mm (connection)
	Internal Hex	3.4, 4.5, 5.7 mm (connection)
Abutment Blanks	External Hex	3.5, 4.1, 5.1 mm (connection) 8 – 12 mm (cylinder)
	Internal Hex	3.5, 4.5, 5.7 mm (connection 8 – 12mm (cylinder)

INTENDED USE:
As established in the Indications for Use Statement:

The CORE 3D abutment system for digital prosthetic solutions are dental abutments placed into a dental implant to provide support for dental prosthetic restorations. The abutments include:

- Titanium Bases to be attached to the underlying implant and upon which a CAD/CAM designed superstructure may be fitted to complete a two-piece dental abutment;
- Titanium Abutment Blanks with a pre-machined implant connection where the upper portion may be custom-milled in accordance with a patient-specific design using CAD/CAM techniques;
- Abutment Screws to permanently fix the abutments to the underlying implant.

Core 3D abutments are intended for use to support single-tooth (unit) and multiple-tooth (bridges and bars) prostheses, in the mandible or maxilla for functional and aesthetic restorations.

Core 3D abutments designed using CAD/CAM techniques must fulfill the Core 3D allowable range of design specifications and be provided as straight abutments only.

Core 3D abutments and are compatible for use with the following dental implants:

- Nobel Biocare® Brånemark System™ (K022562, K934825)
- Zimmer® Tapered Screwvent® (K013227, K061410, K072589)

Abutments are placed into the dental implant to provide support for the prosthetic reconstruction including abutments for cemented restorations to achieve better esthetics. Abutments can be used to restore crowns for single tooth replacements and bridges for multiple tooth restorations.

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SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, the Core 3D Abutment System is compared with the following previously cleared devices:

- NT-Trading (K111935)
- Biohorizons Laser-Lok for Nobel Biocare (K103291)
- Inclusive Dental Solutions – Inclusive Titanium Abutment Blanks (K083192)
- 3M Lava Software (K062493)

Comparison of the proposed devices with the predicate devices is summarized in the following table:

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Summary of comparison with predicate devices	Proposed Device	Predicate Devices			
	Core 3D Abutment System	**K111935** NT-Trading	**K103291** Biohorizons Laser-Lok for Nobel Biocare	**K083192** Inclusive Dental Solutions Inclusive Titanium Abutment Blanks	**K062493** Lava Software
Classification / PROCODE	872.3630 / NHA	872.3630 / NHA	872.3630 / NHA	872.3630 / NHA	872.3630 / NHA / EIH
Intended Use	The CORE 3D abutment system for digital prosthetic solutions are dental abutments placed into a dental implant to provide support for dental prosthetic restorations. The abutments include Titanium Bases to be attached to the underlying implant and upon which a final dental restoration is placed, Titanium Abutment Blanks to be further processed by the dental lab to produce patient-specific abutments and Abutment Screws to permanently fix the abutments to the underlying implant. Core 3D abutments are intended for use to support single-tooth (unit) and multiple-tooth (bridges and bars) prostheses, in the mandible or maxilla for functional and aesthetic restorations. Core 3D abutments are compatible for use with the following dental implants: • Nobel Biocare Brånemark System (K022562, K934825) • Nobel Biocare NobelReplace (K073132, K062566)	Ti-Base Abutments: The devices covered by this submission are abutments which are placed into a dental implant to provide support for a prosthetic restoration. The Ti-Base abutments are intended for use to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple-tooth prosthesis in the mandible or maxilla. The prosthesis can be cement-retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Ti-Base abutments are indicated for use with the following implant systems: · Nobel Biocare® Replace Select® · Nobel Biocare® NobelActive™ · Biomet 3i® Osseotite® · Biomet 3i® Osseotite® Certain® · Nobel Biocare®	Biohorizons Laser-Lok Abutments for Nobel Biocare are intended for use with dental implants as a support for single or multiple unit prostheses in the maxilla or mandible of partially or fully edentulous patients. The abutments are compatible for use with Nobel Biocare™ Nobel Replace™ Straight Groovy™, Nobel Replace™ Tapered Groovy™, NobelSpeedy™ Replace™, Replace™ Select Tapered and Replace™ Select Straight implants with 3.5mm(NP), 4.3mm(RP) and 5.0mm(WP) platform diameter internal tri-channel connections. The abutment screw is intended to secure the abutment to the endosseous implant. Biohorizons Laser-Lok Titanium Base Abutments	The device is indicated for use by dental technicians in the construction of custom-made dental restorations that are supported by endosseous dental implants. The Inclusive Titanium Abutment Blank is intended to be used in conjunction with endosseous implants in the maxillary and/or mandibular arch to provide support for crowns, bridges or overdenture prostheses. The prosthesis can be cement-retained or screw-retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. Inclusive Titanium Abutment Blanks for Nobel Biocare are compatible with NobelActive Internal NP and RP implants. Inclusive Titanium Abutment Blanks for Institut Straumann are	The Lava software is used with 3M ESPE's Lava system, an all-ceramic system for the CAD/CAM fabrication of dental restorations such as inlays, onlays, veneers, crowns and bridges. The software controls the measuring process, processing of the measurement data (3D-CAD tool), and export of the data to the milling machine. In addition, various patient and case information elements can be entered. Other functions are available for verification and service of the measuring system. The Lava software also facilitates the transfer of 3D data from a scanner to a remote milling machine via internet.

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Summary of comparison with predicate devices	Proposed Device	Predicate Devices			
	Core 3D Abutment System	**K111935** NT-Trading	**K103291** Biohorizons Laser-Lok for Nobel Biocare	**K083192** Inclusive Dental Solutions Inclusive Titanium Abutment Blanks	**K062493** Lava Software
	• Nobel Biocare NobelActive (K071370) • Straumann SLActive Implants (K053088) • Straumann P.0004 Implants (K062129) • Biomet 3i Osseotite (K063286) • Biomet 3i Certain (K063341) • Astra Tech OsseoSpeed (K120414) • Zimmer Tapered Screwvent (K013227, K061410, K072589)	Branemark® · Straumann® synOcta® · Straumann® Bone Level® · Zimmer® Tapered Screw-vent® · Astra Tech Osseospeed® · Dentsply-Friadent® Frialit® 2-CONnect Abutments: 2-CONnect abutment is indicated for use to provide support for prosthetic restorations such as bars and bridges. The 2-CONnect abutments can be used in multiple tooth restorations. The 2-CONnect abutment can be used together with cemented bridges and bar constructions for functional and aesthetical reconstruction. The 2-CONnect abutments are indicated for use with the following implant systems: · Nobel Biocare® Replace Select® · Straumann® synOcta® · Straumann® Bone Level®	for Nobel are intended to be used as straight abutments.	compatible with Straumann Bone Level implants in the NC and RC platform sizes. Inclusive Titanium Abutment Blanks for the Nobel Biocare Branemark System are compatible with the Branemark RP size implant. Abutments with angulations greater than 20 degrees on implants less than 4mm in diameter are not indicated for the posterior region because of strength limitations of the implant.	
Materials- Ti Bases, Screws: Abutment Blanks	Ti-6Al-4V Ti-6Al-4V	Ti-6Al-4V Ti-6Al-4V	Ti-6Al-4V Ti-6Al-4V	- Titanium Alloy	-

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Summary of comparison with predicate devices	Proposed Device	Predicate Devices			
	Core 3D Abutment System	**K111935** NT-Trading	**K103291** Biohorizons Laser-Lok for Nobel Biocare	**K083192** Inclusive Dental Solutions Inclusive Titanium Abutment Blanks	**K062493** Lava Software
Form / Features (diameters, height, connection type, anti-rotational features)	Equivalent identical abutment connection geometry and type, including screw geometry for indicated compatible implant systems.	Same diameters / heights / mode of action	Equivalent mating platform geometry.	-	The software provides for 3D modeling for custom forms and features of the superstructure.
Type of retention	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	Screw-retained or cement-retained.	-	Screw-retained to the implant. The prosthesis can be cement-retained to the abutment.	The software provides for 3D modeling for custom forms and features of the superstructure.

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SUMMARY DISCUSSION OF NON-CLINICAL DATA:
The proposed device has been subject to bench testing to determine conformance to performance specifications and requirements taking account of its intended use as an endosseous dental implant abutment and following all indications set out in FDA Document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

Bench testing performed in foreseeable operating conditions included determination of the compatibility of the abutment – implant mating characteristics as well as mechanical compression and fatigue testing – all testing showed correct operation of the device as per its intended use, specifically including dimensional compatibility and mechanical performance testing.

Also, testing included software validation testing of the software system used to ensure that incorporated design limitations correctly prevent the user from milling abutments that do not fulfill the Core3D design criteria.

SUMMARY DISCUSSION OF CLINICAL DATA:
Non-clinical test data are submitted to support this premarket notification and to establish the decision concerning adequate safety and performance of the predicate device. Clinical data are not submitted.

CONCLUSIONS:
We believe the intended use, the indications for use and performance of the Core3D abutment system for digital prosthetic solutions are the same as the intended use, indications for use and performance of the predicate devices. We also believe that the Core3D devices do not suppose any new or increased risk compared with the predicate devices. Based on the information included in this submission, we conclude that the proposed device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

October 24, 2013

Core 3D Protech, S.L.
Ms. Anna Cortina Caixach
Pol. Ind. Santa Anna, Apartat 20
08251 Santpedor
Barcelona Spain

Re: K122295
Trade/Device Name: CORE 3D Abutment System for Digital Prosthetic Solutions
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: II
Product Code: NHA
Dated: October 16, 2013
Received: October 21, 2013

Dear Ms. Caixach:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mary S. Brunner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT
(as required by ODE for all 510(k) received after Jan. 1, 1996)

510(k) Number: **K122295**
Device Name: CORE 3D Abutment System for Digital Prosthetic Solutions
Indications for Use:

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- Zimmer Tapered Screwvent (K013227, K061410, K072589)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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Prescription Use ✓ (21 CFR 801 Subpart D) OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)