DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
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Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

SOADCO S.L.
Maria Mitjaneta
Quality Manager
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ANDORRA

November 16, 2017

Re: K170022
Trade/Device Name: Klockner Vega TiBase For CEREC®
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 9, 2017
Received: October 19, 2017

Dear Maria Mitjaneta:

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,

Mary S. Runner -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): K170022

Device Name: Klockner Vega TiBase for CEREC®

Indications for Use:

The Klockner Vega TiBase for CEREC® abutments are titanium alloy abutments placed onto Klockner Vega Implants to provide support for customized prosthetic restorations. The Klockner Vega TiBase for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Klockner Vega TiBase for CEREC® abutments are to be designed and milled using Sirona CEREC Premium SW 4.2 software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

Prescription Use _____✓_____ AND / OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY
K170022

Date of submission: 2017-11-14

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Device Trade Name: Klockner Vega TiBase for CEREC®
Common Name: Dental Abutments
Classification Name: Endosseous Dental Implant Abutments
Regulation Number: 21 CFR 872.3630
Class: Class II (Special controls)
Panel: Dental
Product code: NHA

Predicate Devices:

510(k) Number Predicate Device	Device Trade Name	Manufacturer
K151324	Straumann® Variobase® for CEREC	Straumann USA, LLC

Reference Devices	510(k) Number	Device Trade Name	Manufacturer
1	K153098	KLOCKNER Vega Dental Implant System	SOADCO, S.L.
2	K111421	Sirona Dental CAD/CAM System	Sirona Dental Systems GmbH
3	K100152	Sirona Dental CAD/CAM System	Sirona Dental Systems GmbH
4	K101732	Astra Tech Implant System, OsseoSpeed TX implants	Astra Tech AB

Device Description:

Klockner Vega TiBase for CEREC® abutments are two-piece abutment (composed of the ti-base component and a ceramic mesostructure or coping) fabricated by using the Sirona Dental CAD/CAM System and are to be used with Klockner Vega Dental Implant Systems, with conical and hexagonal internal connection, platforms MV, NV, RV.
The Klockner Vega TiBase for CEREC® are Ti-base abutments, made of titanium alloy. The coronal portion is designed to interface with the pre-machined mounting hole in the milling blanks compatible with the Sirona CEREC® systems, and the base portion is available in three models to fit three Klockner® dental implant platforms. The new components introduced in this 510(k) are shown below.

Catalog Number (Reference)	Description
18 10 25	NV VEGA Ti-BASE PILAR
18 10 65	RV VEGA Ti-BASE PILAR
18 10 98	MV VEGA Ti-BASE PILAR

The Klockner Vega TiBase for CEREC® abutments are compatible with the previously cleared material inCoris ZI, L size blank (Sirona inCoris ZI meso zirconium dioxide, ZrCO2) within the 510ks K100152 and K111421.

The Klockner Vega TiBase for CEREC® abutments are compatible with copings and crowns fabricated using the following previously cleared mills:
• Sirona Dental CAD/CAM System (introduction of the Sirona SSO series Tibases compatible with the Straumann Tissue Level implants) cleared to market per K100152.

The functionality necessary to design and produce abutments compatible with the Klockner Vega TiBase for CEREC® abutments (as well as the Sirona SSO series Ti-bases) has been verified. Copings and crowns designed using the Premium Sirona CEREC Software version 4.2, within the design limits as defined within the design software, are compatible with the Klockner Vega TiBase for CEREC® abutments. Thus, in order to design prosthetic restorations on Klockner Vega TiBase for CEREC® abutments using Sirona software, compatible scanbodies and Ti-Bases from a defined Sirona library must be chosen and Sirona work-flow, followed. Milling block size and a set of maximum and minimum design parameters are both selectable by the user.

Indications for Use:

The Klockner Vega TiBase for CEREC® abutments are titanium alloy abutments placed onto Klockner Vega Implants to provide support for customized prosthetic restorations. The Klockner Vega TiBase for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations.

All digitally designed copings and/or crowns for use with the Klockner Vega TiBase for CEREC® abutments are to be designed and milled using Sirona CEREC Premium SW 4.2 software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

Substantial Equivalence:

In the establishment of substantial equivalence, Klockner Vega TiBase for CEREC® are compared to the primary predicate device with the same indications for use, the same coronal portion design and similar material (Titanium Alloy). The subject Klockner Vega TiBase for CEREC® abutments are functionally equivalent to the primary predicate Straumann® Variobase® for CEREC® abutments and to the reference device Dental CAD/CAM system abutments (K100152 and K111421). The difference is that the base design portion of these abutments has been designed to interface with the Klockner Vega Implants with conical and hexagonal internal connection, platforms MV, NV, RV and not for the implant platforms which the predicate device describes.

The coronal geometry of the subject devices is equivalent to the coronal geometry of the reference devices (K111421 and K100152), therefore copings and crowns fabricated using the Sirona software and milling systems will be compatible with the subject devices.

There have been no changes to the materials, packaging, or recommended sterilization method parameters for these devices as compared to the reference device Klockner Vega Dental Implant System (K153098).

Indications for use and technological characteristics have been compared with the predicate device and reference devices (see next pages), following the guidelines set out in guidance document “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments”.
Features of proposed device not shared with predicate devices have been substantiated using a reference device.

All issues affecting safety and performance have been reviewed and discussed. Any differences have been addressed in the bench testing performed on the proposed device.

Device	Indications for Use
Proposed device: Klockner Vega TiBase for CEREC®	• The Klockner Vega TiBase for CEREC® abutments are titanium alloy abutments placed onto Klockner Vega Implants to provide support for customized prosthetic restorations. The Klockner Vega TiBase for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. • All digitally designed copings and/or crowns for use with the Klockner Vega TiBase for CEREC® abutments are to be designed and milled using Sirona CEREC Premium SW 4.2 software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.
Predicate device: K151324 Straumann® Variobase® for CEREC®	• The Straumann® Variobase® for CEREC® are titanium alloy abutments placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase® for CEREC® abutments are indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. • All digitally designed copings and/or crowns for use with the Straumann® Variobase® for CEREC® abutments are to be designed using Sirona inLab software (Version 3.65 or higher) or Sirona CEREC Software (Version 4.2 or higher) and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.
Reference device 1: K153098 KLOCKNER Vega Dental Implant System	• The KLOCKNER® VEGA® dental implant system is indicated to replace missing teeth in single and multiple unit applications within the mandible or maxilla. Implants can be for immediate placement and function in extraction sites and partially or completely healed alveolar ridge situations, when good primary stability is achieved and with appropriate occlusal loading. Different loading protocols (immediate, early or delayed) can be applied in partially or totally edentulous patients. The prosthetic restorations can be single-unit or multiple-unit restorations. • The Ø 3.0 mm implants should only be used for unit restorations for maxillary lateral incisors and mandibular lateral and central incisors.

Device	Indications for Use
Reference device 2: K111421 Sirona Dental CAD/CAM System	The Sirona Dental **CAD/CAM** System is intended for use in partially or fully edentulous mandibles and maxilla in support of single or multiple-unit cement retained restorations. For the titanium bases **SSO 3.5** L and SBL **3.3** L, the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and **CAD/CAM** software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base **CAD/CAM** (types K2244.xxxx) (K083496) in the Camlog Implant System. The **CAD/CAM** software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems: * Nobel Biocare Replace (K020646) * Nobel Biocare Branemark (K022562) * Friadent Xive **(K013867)** * Biomet 3i Osseotite (K980549) * Astra Tech Osseospeed (K09 1239) * Zimmer Tapered Screw-Vent (K0614 **10)** * Straumami SynOcta **(K061 176)** * Straumann Bone Level **(K053088,** K062 129, **K060958)** * Biomet 3i Certain (K014235, **K061629)** * Nobel Biocare Active **(K071370)**
Reference device 3: K100152 Sirona Dental CAD/CAM System	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxilla in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems: ** Nobel Biocare Replace (K020646)* ** Nobel Biocare Branemark (K022S62)* ** FriadentXive (1K013867)* ** Biomet 3/ Osseotite (K980S49!)* ** Astra Tech Osseospeed (K09 1239)* ** Zimmer Tapered Screw- Vent (K(061410)* ** Straumann SynOcta (K(061176)*

Device	Indications for Use
Reference device 4: K101732 Astra Tech Implant System, OsseoSpeed TX implants	The OssseoSpeed implants are intended to be used: • to replace missing teeth in single and multiple unit applications within the mandible or maxilla • for immediate placement in extraction sites and partially or completely healed alveolar ridge situations • for both one- and two-stage surgical procedures • especially well in soft bone applications where implants with other implant surface treatments may be less effective • together with immediate loading protocol in all indications, except in single tooth situations in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate • together with immediate loading protocol for single-tooth restorations on implants 8 mm or longer • with its 3.0 S product line for maxillary lateral incisors and mandibular lateral and central incisors.
Equivalence Discussion	Substantially equivalent in reference the coronal portion of proposed device respect the predicate Device. Coronal aspect of proposed device is designed to interface with copings/crowns fabricated from milling blanks containing pre-machined holes for use with the CEREC® CADCAM system which is the same than predicate device and the reference device 2 and 3. The workflows used to design and fabricate the restorations are the same than the predicate device and the reference device 2 and 3. The base design portion of the proposed device has been designed to interface with the Klockner Vega Implants; therefore these implants are different than the predicate devices but are the same than the reference device 1 and substantial equivalence to the reference device 4. The prosthetic restorations are the same for all predicate devices and reference devices.

Features	PROPOSED DEVICE: Klockner Vega TiBase for CEREC®	PREDICATE DEVICE: K151324 (Straumann® Variobase® for CEREC®)	REFERENCE DEVICE 1: K153098 (Klockner Vega Dental Implant System)	REFERENCE DEVICE 2 / 3: K100152 / K111421 (Sirona Dental CAD/CAM System)	REFERENCE DEVICE 4: K101732 (Astra Tech Implant System, OsseoSpeed TX implants)	Equivalence Discussion
Ti-base Material	Titanium-Aluminium-Vanadium Alloy (Ti-6Al-4Va)	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	Titanium-Aluminium-Vanadium Alloy (Ti-6Al-4Va) for the abutments	Titanium-Aluminium-Vanadium Alloy (Ti-6Al-4Va)	Titanium-Aluminium-Vanadium Alloy (Ti-6Al-4Va) for the abutments	Substantially equivalent. All materials are Titanium alloy.
Coping/Crown Material	Compatible with the Sirona Dental System inCoris ZI Meso L (K100152 / K111421).	Compatible with any milling blanks cleared for use with the CEREC MC X and MC XL milling systems (i.e., containing the pre-machined mounting hole). Currently available: inCoris ZI meso (K123664) Ivoclar IPS e.max CAD (K132209) Ivoclar Telio CAD (K093708)	N/A	Sirona Dental System inCoris ZI Meso L	N/A	Same
Implant Compatibility	Klockner Vega Implants (bone level)	Straumann implants (tissue level and bone level)	Vega Klockner Implants (bone level)	Nobel Biocare / Friadent / Biomet 3i / Astra Tech / Zimmer / Straumann (tissue level and bone level)	Astra Tech implants (bone level)	Substantially Equivalent
Design – Abutment Diameter (base) mm	4.5 - 7	4.5 - 7	3.65	3.3., 3.4, 3.5, 3.8, 4.0, 4.1, 4.3, 4.5, 4.8, 5.0, 5.5, 5.7, 6.0, 6.5		Same

Features	PROPOSED DEVICE: Klockner Vega TiBase for CEREC®	PREDICATE DEVICE: K151324 (Straumann® Variobase® for CEREC®)	REFERENCE DEVICE 1: K153098 (Klockner Vega Dental Implant System)	REFERENCE DEVICE 2 / 3: K100152 / K111421 (Sirona Dental CAD/CAM System)	REFERENCE DEVICE 4: K101732 (Astra Tech Implant System, OsseoSpeed TX implants)	Equivalence Discussion
Design – Abutment Height (mm)	4.7	4.7	4.7	4.7	4.7	Same
Abutment Angulation	up to 20°	up to 20°	N/A	up to 20°	up to 20°	Same
Design Workflow	Per the Premium Sirona CEREC, software version 4.2.	Per the Sirona CEREC InLab, software version 3.6 or later.	N/A	Per the Sirona Dental CAD/CAM Software.	N/A	Substantially equivalent
Manufacturing Workflow	Per Sirona Cerec milling systems	Per the Sirona Cerec MC X and MC XL milling systems	N/A	Per Sirona Cerec milling systems	N/A	Same
Mode of Attachment	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Screw-retained or cement retained	Same
Reusable	No	No	No	No	No	Same
Sterility	Provided non-sterile. These devices are individually packed and provided non-sterile, but intended to be sterilized before placement in the mouth. Instructions for use contain the recommended sterilization process validated as per standard ISO 17665-1 and standard ISO/TS 17665-2.	Predicate devices are also provided non-sterile. As proposed devices, these predicates are individually packed and provided non-sterile, but intended to be sterilized before placement in the mouth. The same sterilization process (validated as per ISO 17665-1) is recommended.	Reference devices are also provided non-sterile. As proposed devices, these predicates are individually packed and provided non-sterile, but intended to be sterilized before placement in the mouth. The same sterilization process (validated as per ISO 17665-1) is recommended.	Reference devices are also provided non-sterile. As proposed devices, these predicates are individually packed and provided non-sterile, but intended to be sterilized before placement in the mouth. The same sterilization process (validated as per ISO 17665-1) is recommended.	Reference devices are also provided non-sterile. As proposed devices, this predicate is individually packed and provided non-sterile, but intended to be sterilized before placement in the mouth. The same sterilization process (validated as per ISO 17665-1) is recommended.	Same

Summary Discussion of Non-Clinical Data:

- Biocompatibility

All materials used in the manufacture of Klockner Vega TiBase for CEREC® have been subject to biological evaluation taking account the intended use of the devices and the nature and duration of contact with the patient. Requirements of applicable recognized standards have been considered and, when appropriate, biological testing has been performed:

- Biocompatibility of the subject devices is confirmed by conformance to FDA recognized consensus material standards (titanium alloy conforming to ASTM F136). The manufacturing processes and materials for the Ti Base are identical to those used for Klockner Implant System components previously cleared in K153098.

- Sterilization

Klockner Vega TiBase for CEREC® abutments have been subject to bioburden and sterility testing in accordance with ISO 11737-1 and ISO 11737-2, respectively. Steam sterilization validation according to ISO 17665-1 and ISO/TS 17665-2 has been carried out to confirm the sterilization parameters.

- Bench testing
  - Dimensional verification assuring the compatibility with Sirona InCoris blocks and the appropriate fit of the milling coping on the abutment.
  - Laboratory bench testing, including dimensional analysis and dynamic fatigue and bending assays, has been performed considering worst-case conditions for the Klockner Vega TiBase for CEREC® abutments with cemented InCoris coping according to ISO 14801 *Dentistry. Implants. Dynamic fatigue test for endosseous dental implants.*
  - Process validation of the Klockner Vega TiBase for CEREC® within the Sirona CEREC® workflow.

Summary Discussion of Clinical Data:
No clinical data are included in this submission.

Conclusions:
We consider that the intended use, the indications for use, the operation principle and the technological characteristics of Klockner Vega TiBase for CEREC® are equivalent to those of predicate devices. The documentation submitted in this premarket notification confirms that, even though minor technological differences may exist, the submission device is substantially equivalence to the predicate devices. Therefore, substantial equivalence of Klockner Vega TiBase for CEREC® to the predicate devices may be established.