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510(k) SUMMARY

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Device Trade Name: Klockner Dental Implant Abutments
Common Name: Endosseous Dental Implant Abutments
Classification Name: Endosseous Dental Implant Abutment (21 CFR 872.3630)
Product code: NHA

Legally Marketed (Predicate) Device(s):

510(k) Number	Device	Manufacturer
K080224	Klockner Essential Dental Implant System, models: EC, ES, ECK	SOADCO
K082200	Klockner Essential Dental Implant System, model: EC 1.5	SOADCO
K010132	Klockner Dental Implants, models SK2, NK2, S4	SOADCO
K062129	P.004 implants including abutments and healing caps	Straumann
K071585	NC Healing Abutments and NC Closure Screws	Straumann
K033243	ITI synOcta (Esthetic) Meso Abutments	Straumann
K071357	P.004 NC Anatomic Abutments	Straumann
K050705	TiUnite implants	Nobel Biocare
K992334	TiN Coated Implants and Abutments	3i
K060291	PreFormance Temporary Cylinders	3i
K072624	Abutment for Provisional Restorations	Astra Tech
K092248	SPI® Customizable gingiva former	Thommen Medical AG
K101798	SPI® Variomulti Angled abutment	Thommen Medical AG
K083876	SFI-Bar®	Cendres & Métaux
K102804	SPI® Titanium Base for CADICAM	Thommen Medical AG
K072055	Lava™ Frame, Lava™ Frame Shade	3M ESPE AG

Device Description:

Klockner Dental Implant Abutments consist of a group of prosthetic components placed into dental implants to aid in prosthetic rehabilitation. According to their function, they are classified in:

- Healing caps, are manufactured in Titanium Alloy, intended to assist in healing or modification of the adjacent tissues for internal octagonal connection system.
- Protective caps, manufactured in PMMA and Titanium Alloy intended to protect abutments when choosing direct oral impression for internal octagonal connection system.
- Temporary abutments, manufactured in Titanium cp, Titanium Alloy and Titanium cp + PMMA, intended to support provisional prosthetic restorations for internal octagonal connection system.
- Angled abutments, manufactured in Titanium cp and Titanium Alloy, intended to retain definitive dental prosthesis. Used when it is necessary to correct the implant axis, for internal octagonal connection system and external hexagonal connection system.
- Straight abutments, manufactured in Titanium Alloy and Titanium cp, intended to retain definitive dental prosthesis for internal octagonal connection system. Includes Titanium Octacone Scan abutment, a Titanium Base for CAD/CAM. This base is suitable for precision fit custom abutments or crown and bridge restorations fabricated with CAD/CAM technology provided separately by 3M ESPE as the Lava System.
- Overdenture abutments, manufactured in Titanium Alloy and POM C, intended to retain removable dental prosthesis for internal octagonal connection system and external hexagonal connection system.

Healing caps, protective caps and temporary abutments are used for a limited time, while angled abutments, straight abutments and overdenture abutments are intended for a definitive use.

Intended Use:

The Klockner Dental Implant Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges or overdentures. The Klockner Dental Implant Abutments include healing caps, protective caps, temporary abutments, angled abutments, straight abutments, and overdentures. All abutments are intended to be used with the Klockner Dental Implant Systems, models: Essential EC, Essential ES, Essential ECK, Essential EC 1.5, SK2 and NK2.

Summary of Comparison with Predicate Device:

In the establishment of substantial equivalence, KLOCKNER dental implant abutments are compared with other similar abutments already available on the market as indicated above.

OSED ice	Indications for Use / Intended Use	Material	Restoration	Basic Design
er ents	The Klockner Dental Implant Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges or overdentures. The Klockner Dental Implant Abutments include healing caps, protective caps, temporary abutments, angled abutments, straight abutments, and overdentures. All abutments are intended to be used with the Klockner Dental Implant Systems, models: Essential EC, Essential ES, Essential ECK, Essential EC 1.5, SK2 and NK2.	**Healing/protective caps:** Titanium ASTM F136 (healing caps, protective caps) PMMA (protective caps) **Temporary abutments:** Titanium ASTM F67 (temporary Octacone/Esthetic Octacone) PMMA (temporary Esthetic Octacone) Titanium ASTM F136 (circular fittings, fixation screws) **Angled/straight abutments:** Titanium ASTM F67 (angled abutments, straight octacone scan	Single or multi-unit	**Healing/protective caps:** Conical emergence profile. Beveled design. **Temporary abutments:** External retentions to promote the union of acrylic material with the abutment (temporary Octacone, circular fittings). Acrylic-based polymer with a titanium base (only for the temporary Esthetic Octacone) Standard and wide platforms. Conical connection to enable insertion of multiple structures. **Angled/straight abutments:** Angled octagonal abutments (17°, 22°, 30°) and hexagonal abutment (30°), with occlusal thread to screw on the abutment head. Anodized angled abutments (17°, 22°). Straight pillar abutment (ref. 10 10 15). 25° conicity Straight octacone scan (titanium bonding base for CAD/CAM). Standard platform. **Overdenture abutments:** Ball attachment design. Abutment implant connection: screw fixation.Connecting

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		abutment) Titanium ASTM F136 (straight pillar abutment, screws) **Overdenture abutments:** Titanium ASTM F136 TiN coating POM C (cap)		principle overdenture: retentive system. TiN treatment.

PREDICATED DEVICE

Predicate Device	Indications for Use / Intended Use	Material	Restoration	Basic Design
K080224 Klockner Essential Dental Implant System, models: EC, ES, ECK	The Klockner Essential implant system is especially designed for surgical insertion into the bone using additional material to replace the root of the teeth, acting as the support for the dental implants formed by implant accessories. The Essential Solid implants are fitted with an internal octagonal conical connection combined with an external octagonal connection measuring 1.2 mm in height. The Essential Cone implants are fitted with an internal octagonal conical connection. The Essential ECK implants are fitted with a larger internal octagonal conical connection than that of the Essential Cone implants. Immediate loading is appropriate for the Essential Solid, Essential Cone and Essential ECK implants when good primary stability is achieved with appropriate occlusal loading. Abutments can be used in single tooth replacements and	**Healing/protective caps:** Titanium (K062129, K071585, K071357: healing caps and protective caps) Titanium ASTM F136 (K080224) POM C (K080224) **Temporary abutments:** Titanium ASTM F136 (K072624, K092248, K060291, Implant System 3i DIEM™)	Single or multi-unit	**Healing/protective caps:** Beveled design. **Angled/straight abutments:** Octagonal angled abutment design (17° and 22°), but without the occlusal thread. Also anodized abutments (blue and green) Similar pillar abutment design. Standard platform. **Overdenture abutments:** Ball attachment design. Abutment implant connection: screw fixation. Connecting principle overdenture: retentive system. TiN treatment.

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	multiple tooth restorations. 8mm Implants are not indicated for use as unitary implants and for immediate load.	PEEK (K060291, Implant System 3i DtEM™) PMMA (K092248) **Angled and straight abutments:** Titanium ASTM F67 (K080224, K033243, K062129, K101798, K102804: octagonal angled abutments, straight octacone scan abutment) Titanium (K050705: hexagonal angled abutment) Titanium ASTM F136 (K080224: straight pillar abutment, screws) **Overdentures abutments:** Titanium ASTM F136 (K010132, K080224, K083876) Titanium (K033243) TiN coating (K010132, K080224, K992334) POM C (K010132, K080224)		
K010132 Klockner Dental Implants, models SK2, NK2, S4	The dental implant consist of a small conical fixture (the root-form configuration), perhaps six to eighteen millimetres in length, placed into a tiny receptacle channel which has been drilled into the bone under the gingiva (gum) at the desired location. The gingiva is elevated fi-on the underlying bone, the channel is cut, the fixture is placed, and the gingiva is sutured. In its simplest form, the implant is used to substituting the roots of teeth, to secure a denture. This is a wonderful remedy for an edentulous patient whose ridges do not allow the secure placement of a denture. In other' uses the implant becomes the support for a single crown, sometimes two or more (sometime many) implants are used to support a bridge or multiple bridge.		Single or multi-unit	**Overdenture abutments:** Ball attachment design. Abutment implant connection: screw fixation. Connecting principle overdenture: retentive system. TiN treatment.
K062129 P.004 implants including abutments and healing caps	The P.004 implants are intended for immediate, delayed or conventional placement in the maxilla and/or mandibular arches to support crowns, bridges or overdentures in edentulous or partially edentulous patients. They are intended for immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used. Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. Meso abutments are indicated for cemented restorations particularly in esthetic areas of the mouth. The abutment can be used in single tooth replacements and multiple		Single or multi-unit	**Healing/protective caps:** Conical emergence profile. **Angled abutments:** Angled abutment design. Standard platform.

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	tooth restorations.			
K071585 Straumann NC Healing Abutments and NC Closure Screws	P.004 Healing abutments and Closure Screws are intended for use with the Straumann P.004 Bone Level Implant system to protect the inner configuration of the implant. Healing abutments have a secondary function to maintain, stabilize and form the soft tissue during the healing process.		N/A	**Healing/protective caps:** Conical emergence profile
K033243 Straumann ITI synOcta (Esthetic) meso abutments	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns or bridges. The ITI synOcta Meso Abutments are indicated for cemented restorations in esthetic areas of the mouth. The abutment can be used in single-tooth replacements and multiple-tooth restorations.		Single or multi-unit	**Angled/straight abutments:** Octagonal angled abutment design (15° and 20°). Titanium Base (for CAD/CAM) design. Standard platform. **Overdenture abutments:** Ball attachment design. Connecting principle overdenture: retentive system.
K071357 Straumann P.004 NC Anatomic Abutments	Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges and overdentures. Abutments can be used in single tooth replacements and multiple tooth restorations.		Single or multi-unit	**Healing/protective caps:** Beveled design.
K050705 Nobel Biocare TiUnite Implants	Nobel Biocare TiUnite Implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare TiUnite Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare TiUnite Implants may be placed immediately and put into immediate function providing		Single or multi-unit	**Angled abutments**: Angled hexagonal design. Standard platform.

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	that the initial stability requirements detailed in the surgical manuals are satisfied. TiUnite implants are indicated for use in soft bone whenever immediate or early loading is applied. The TiUnite implants are preferred in these soft bone indications because bone formation is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration and higher success rates.			
K992334 3i TiN Coated Implants and Abutments	Endosseous implants and abutments are indicated for surgical placement into the upper and lower jaw arches as permanent support for prosthetic appliances to restore a patient's masticatory function. Proposed Titanium Nitride ("TiN") coating applied to implants / abutments improves the overall esthetics of the completed restoration.		Single or multi-unit	**Overdenture abutments:** TiN treatment
K060291 3i PreFormance Temporary Cylinders	The PreFormance Temporary Cylinders are intended for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. They are intended for use to support single and multiple unit prostheses in the mandible or maxilla for up to 180 days during endosseous and gingival healing, and are for non occlusal loading of single and multiple unit provisional restorations. The prostheses can be screw or cement retained to the abutment.		Single or multi-unit	**Temporary abutments:** Acrylic-based polymer with a titanium base.
K072624 Astra Tech Abutments for Provisional Restorations	Astra Tech Implant System abutments are intended to be used in conjunction with Astra Tech Implant System implants in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures.		Single or multi-unit	**Temporary abutments:** External retentions to promote the union of acrylic material with the abutment. Conical connection to enable insertion of multiple structures.
K101798 SPI® VARIOmulti	Thommen SPI® VARIOmulti Angled Abutments are intended to be used in conjunction with SPI®' System dental implants in the maxillary and/or mandibular arch to provide support for splinted		Single or multi-unit	**Angled abutments:** Angled abutments design (17°, 22° and 30°).

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Angled Abutment	crowns, bridges or overdentures.			Standard platform.
K092248 SPI® Customizable Gingiva Former	The SPI® Customizable Gingiva Former is intended to be used in conjunction with SPI® System dental implants to provide temporary support for crowns or bridges in the maxillary and/or mandibular arch.		Single or multi-unit	**Temporary abutments:** Acrylic-based polymer with a titanium base. Standard platform and conical connection to enable insertion of multiple structures.
K083876 SFI-Bar® abutment	The SF1-Bar® is intended to be used with the SPI Element Platform 4.0 mm implant (K070007) to provide support for fixation of overdentures.		Multi-unit	**Overdenture abutments:** Abutment implant connection: screw fixation. Connecting principle overdenture: retentive system.
K102804 SPI® Titanium Base for CAD/CAM	Thommen Titanium Base for CAD/CAM abutments are intended to be used in conjunction with Thommen implants and the 3M ESPE Lava™ System in the maxillary and/or mandibular arch to provide support for crowns and bridges.		Single or multi-unit	**Straight abutments:** Titanium Base (for CAD/CAM) design.

Design features, technological characteristics and specifications of the proposed devices have been compared with those of the predicate devices following the guidelines set out in guidance document "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" (May 12, 2004). Any differences have been addressed in the different bench tests performed on the proposed devices and all issues affecting safety and performance have been reviewed and discussed.

Specific references included in the proposed device share indications for use, basic design, operating principles, material and packaging with other specific predicate devices.

Summary Discussion of Non-Clinical Data:

The KLOCKNER dental implant abutments have been subject to bioburden and sterility testing in accordance with ISO 11737-1 and ISO 11737-2 and the applicable requirements taking account of their intended use. A sterilization validation according ISO 17665-1 was carried

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out to confirm the recommended sterilization parameters. Laboratory bench testing including torsion and fatigue testing (according ISO 14801) in worst-case conditions were performed and showed acceptable device performance as per its intended use. Biocompatible raw materials have been used for manufacturing the abutments.

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Summary Discussion of Clinical Data:

No clinical data are presented in this submission.

Conclusions:

We believe the intended use, the indications for use, the mode of operation and performance characteristics of the KLOCKNER Dental Implant Abutments are equivalent to the indicated predicate devices. The results of bench testing confirm acceptable device performance as per its intended use. Therefore we believe substantial equivalence of the KLOCKNER Dental Implant Abutments to the predicate devices may be established.

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

July 19, 2013

Ms. Maria Mitjaneta
Quality Manager
Soadco, S.L.
Avgda. Fiter i Rossell, 4bis –Local 2
Escaldes – Engordany
Andorra AD-700

Re: K122988
Trade/Device Name: KLOCKNER Dental Implant Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 5, 2013
Received: July 12, 2013

Dear Ms. 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 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,

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

INDICATIONS FOR USE

510(k) Number (if known): K122988

Device Name: KLOCKNER Dental Implant Abutments

Indications for Use:

The Klockner Dental Implant Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges or overdentures. The Klockner Dental Implant Abutments include healing caps, protective caps, temporary abutments, angled abutments, straight abutments, and overdentures. All abutments are intended to be used with the Klockner Dental Implant Systems, models: Essential EC, Essential ES, Essential ECK, Essential EC 1.5, SK2 and NK2.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen
2013.07.19 09:13:57 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122988