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

January 29, 2016

SOADCO, S.L.
Ms. Maria Mitjaneta
Quality Manager
Avgda Fiter I Rosell., 4 Bis-local 2
Escaldes-Engordany, AD-700
ANDORRA

Re: K151194
Trade/Device Name: Klockner Dental Implant Abutments (II)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 16, 2015
Received: December 28, 2015

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 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,

for 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

INDICATIONS FOR USE

510(k) Number (if known): K151194

Device Name: Klockner Dental Implant Abutments (II)

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. The Klockner Dental Implant Abutments include protective cap, temporary abutment, angled abutments, straight abutments, cast abutments. All abutments are intended to be used with the Klockner Dental Implant Systems, models: Essential EC, Essential EC 1.5.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (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 K151194

Date of Preparation of Summary: January 25, 2016

Submitter/owner name: SOADCO, S.L.
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Device Trade Name: Klockner Dental Implant Abutments (II)
Common Name: Dental Abutments
Classification Name: Endosseous Dental Implant Abutments
Regulation Number: 21 CFR 872.3630
Class: Class II
Panel: Dental
Product code: NHA

Legally Marketed (Predicate) Device:

PREDICATE DEVICE 510(k) Number	Device Trade Name	Manufacturer
K122988	Klockner Dental Implant Abutments	SOADCO S.L.

Device Description:
Klockner Dental Implant Abutments (II) consist of a group of prosthetic components to be used with dental implants as an aid in prosthetic rehabilitation. According to their function, they are classified in:

- Protective cap, made of titanium alloy, intended to be provisionally connected to dental abutment as a protection when choosing direct oral impression on the abutment.
- Temporary abutment, made of titanium alloy, intended to be provisionally connected to dental abutment to retain a provisional screw-retained multiple-unit restoration.
- Angled abutments, made of titanium alloy, intended to be definitively connected to dental implant to enable screw-retained multiple-unit restorations. These abutments, used when it is necessary to correct prosthesis axis with respect to implant axis, are available with different angulation and different transmucosal height, enabling the anatomic characterization of the gum margin and facilitating the prosthetic fitting.

- Straight abutments, made of titanium alloy, intended to be definitively connected to dental implant to enable screw-retained multiple-unit restorations, with not correction of implant angulation. These abutments are available with different transmucosal height, enabling the anatomic characterization of the gum margin and facilitating the prosthetic fitting.
- Cast abutments, made of gold alloy and Co-Cr-Mo alloy, intended for cement-retained single-unit and multiple-unit restorations and for screw-retained single-unit restorations on dental implants using the casting technique.

All these abutments are designed for Klockner Dental Implant Systems, models Essential EC (K080224) and Essential EC 1.5 (K082200), with internal octagonal cone connection.

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. The Klockner Dental Implant Abutments include protective cap, temporary abutment, angled abutments, straight abutments, cast abutments. All abutments are intended to be used with the Klockner Dental Implant Systems, models: Essential EC, Essential EC 1.5.

Summary of Comparison with Predicate Device:
In the establishment of substantial equivalence, Klockner Dental Implant Abutments (II) are compared to a legally marketed device with the same intended use.
Proposed device intended use, indications for use and technological characteristics have been compared with those of predicate device (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 device have been substantiated using two reference devices. These differences are not considered to raise different questions of safety and effectiveness than the predicate.
All issues affecting performance have been reviewed and discussed. Any differences have been addressed in the bench testing performed on the proposed device.

REFERENCE DEVICE 510(k) Number	Device Trade Name	Manufacturer
K080224	Klockner Essential Dental Implant System	SOADCO S.L.
K121843	NP-Cast Abutment System	OSSTEM Implant Co., Ltd.

NOTE: Numbers noted as ‘ref. xx xx xx’ (where x means a number) in the table below refer to specific catalog numbers of devices in the Klockner Implant System.

Features	PROPOSED DEVICE: Klockner Dental Implant Abutments (II)	PREDICATE DEVICE K122988 (Klockner Dental Implant Abutments)	REFERENCE DEVICE K080224 (Essential Implant System)	REFERENCE DEVICE K121843 (NP-Cast Abutment System)
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. The Klockner Dental Implant Abutments include protective cap, temporary abutment, angled abutments, straight abutments, cast abutments. All abutments are intended to be used with the Klockner Dental Implant Systems, models: Essential EC, Essential EC 1.5.	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.	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 multiple tooth restorations. 8mm Implants are not indicated for use as unitary implants and for immediate load.	NP-Cast Abutment System is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Design – Protective cap	- EC multi-cone protective cap (ref. 10 05 16) Protective cap intended to be provisionally connected (contact ≤ 6 months) to 30º and 17º angular Octacone® multi-cone abutments (ref. 10 10 37, 10 10 38, 10 10 43, 10 10 44, 10 10 45) included in this submission, and also to 30º angular abutment multi-cone [occlusal screw] (ref. 10 10 36) cleared in K122988, in order to cover and protect their inner configuration when choosing direct oral impression on these abutments.	Proposed device has the same intended use and is functionally equivalent to these predicate devices: - EC 12º protective cap (ref. 10 05 14) - EC 25º protective cap (ref. 10 05 15) These devices are also connected to dental abutments in order to cover and protect their inner configuration when performing direct oral impression on them.	N/A	N/A

Features	PROPOSED DEVICE: Klockner Dental Implant Abutments (II)	PREDICATE DEVICE K122988 (Klockner Dental Implant Abutments)	REFERENCE DEVICE K080224 (Essential Implant System)	REFERENCE DEVICE K121843 (NP-Cast Abutment System)
Design – Temporary abutment	- Circular Ti fitting - EC multi-cone (ref. 10 13 16) Abutment intended to be provisionally connected (contact ≤ 6 months) to 30º and 17º angular Octacone® multi-cone abutments (ref. 10 10 37, 10 10 38, 10 10 43, 10 10 44, 10 10 45) included in this submission, and also to 30º angular abutment multi-cone [occlusal screw] (ref. 10 10 36) cleared in K122988, for retaining a provisional screw-retained multiple-unit restoration while definitive prosthesis is manufactured.	Proposed device has the same intended use and is functionally equivalent to this predicate device: - Circular Ti Fitting - EC 25º (ref. 10 13 15) This device is also provisionally connected to dental abutment to retain a provisional screw-retained multiple-unit restoration while definitive prosthesis is manufactured.	N/A	N/A
Design – Cast abutments	Abutments intended for cement-retained single-unit and multiple-unit restorations and for screw-retained single-unit restorations on Essential Cone dental implants, using casting technique. The design consists on a metal-based part with a casting part over-injected in plastic (burned-out in casting process): - G Gold Octacone® abutment (ref. 10 10 13 G): gold cast abutment intended to be connected to wide platform Essential Cone implants. - Co-Cr Octacone® abutment (ref. 10 10 16): Co-Cr cast abutment intended to be connected to regular platform Essential Cone implants. - G Co-Cr Octacone® abutment (ref. 10 10 16 G): Co-Cr cast abutment intended to be connected to wide platform Essential Cone Implants.	N/A	Proposed devices have the same intended use and are functionally equivalent to reference device: - Gold Octacone® Abutment (ref. 10 10 13): connected to regular platform Essential Cone implants. This abutment is also intended for cement-retained single-unit and multiple-unit restorations and for screw-retained single-unit restorations on Essential Cone dental implants, using casting technique. The design also consists on a metal-based part with a casting part over-injected in plastic (burned-out in casting process).	N/A

Features	PROPOSED DEVICE: Klockner Dental Implant Abutments (II)	PREDICATE DEVICE K122988 (Klockner Dental Implant Abutments)	REFERENCE DEVICE K080224 (Essential Implant System)	REFERENCE DEVICE K121843 (NP-Cast Abutment System)
Design – Straight abutments	Straight abutments intended to be connected to Essential Cone dental implants (regular platform) for screw-retained multiple-unit restorations, with not correction of implant angulation. Designed with top conical shape (25º respect to the implant axis) to make easier the placement of the multiple-unit restoration, allowing the correction of possible divergences among the axis of the implants involved. Available with different height from implant platform and different transmucosal height (TH) for enabling the anatomic characterization of the gum margin and facilitating the prosthetic fitting: - 25º Pillar abutment - [2.5 MM] - [TH 1 MM] (ref. 10 10 40) - 25º Pillar abutment - [4 MM] - [TH 2.5 MM] (ref. 10 10 41) - 25º Pillar abutment - [5.5 MM] - [TH 4 MM] (ref. 10 10 42)	Proposed devices have the same intended use and are functionally equivalent to predicate device: - 25º pillar abutment - 1mm (ref. 10 10 15) This abutment is also intended to be connected to Essential Cone dental implants for screw-retained multiple-unit restorations, with not correction of implant angulation. It is designed with the same top conical shape (25º respect to the implant axis) as that of proposed devices, with 1 mm of height from implant platform and without transmucosal height (TH = 0).	N/A	N/A
Design – Angled abutments	Abutments with angulation that modifies the prosthesis axis respect to the implant axis. Intended to be connected to Essential Cone dental implants (regular platform) for screw-retained multiple-unit restorations. Available with different angulation (30º and 17º) and different transmucosal height (TH)[1] for enabling the anatomic characterization of the gum margin and facilitating the prosthetic fitting: - 30º angular Octacone® multi-cone abutment [TH 4 mm] (ref. 10 10 37) - 30º angular Octacone® multi-cone abutment [TH 5 mm] (ref. 10 10 38) - 17º angular Octacone® multi-cone abutment [TH 2 mm] (ref. 10 10 43) - 17º angular Octacone® multi-cone abutment [TH 3 mm] (ref. 10 10 44) - 17º angular Octacone® multi-cone abutment [TH 4 mm] (ref. 10 10 45)	Proposed devices have the same intended use and are functionally equivalent to predicate device: - 30º angular abutment multi-cone [occlusal screw] (ref. 10 10 36) This abutment is also intended to be connected to Essential Cone dental implants and be used for screw-retained multiple-unit restorations. It is designed with 30º angulation that modifies the prosthesis axis respect to the implant axis, and with transmucosal height (TH)[1] of 3 mm.	N/A	N/A

[1] Transmucosal height (TH) is the distance between implant platform [implant-abutment connection] and prosthetic platform [abutment-prosthesis connection].

Features	PROPOSED DEVICE: Klockner Dental Implant Abutments (II)	PREDICATE DEVICE K122988 (Klockner Dental Implant Abutments)	REFERENCE DEVICE K080224 (Essential Implant System)	REFERENCE DEVICE K121843 (NP-Cast Abutment System)
Material / Composition	- Titanium alloy (ASTM F136, ISO 5832-3): used in protective cap, temporary abutment, straight abutments and angled abutments. - Gold alloy 6019: used in gold cast abutment. - Co-Cr-Mo alloy (ASTM F1537 alloy 1, ASTM F799, ISO 5832-12): used in Co-Cr cast abutments. - POM C: used in casting part of cast abutments (material not intended to be in contact with the patient, since it is burned-out during the casting process of the abutments).	- Titanium alloy (ASTM F136, ISO 5832-3): used in protective caps, temporary abutment and straight abutment.	- Gold alloy 6019: used in Gold Octacone® Abutment. - POM C: used in casting part of Gold Octacone® Abutment.	- Co-Cr-Mo alloy: used in NP-Cast Abutment System.
Sterility	All devices (protective cap, temporary abutment, cast abutments, straight abutments and angled abutments) are 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.	Predicate devices (protective caps, temporary abutment, straight abutment and angled abutment) 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 device (cast abutment) is also provided non-sterile. As proposed devices, this reference device 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.	N/A

Summary Discussion of Non-Clinical Data:

- Biocompatibility
  All materials used in the manufacture of Klockner Dental Implant Abutments (II) have been subject to biological evaluation taking account the intended use of the devices and the nature and duration of contact with the patient, according to the requirements of applicable recognized standards ISO 10993-1:2009 and ISO 7405:2008. In the case of Co-Cr cast abutments, the potential degradation of the material in biological environments has also been contemplated; corrosion resistance and galvanic corrosion assays have been carried out according to ISO 10993-15, ASTM F746 and ASTM G71, and test results confirm the high corrosion resistance of Co-Cr-Mo alloy and show an insignificant galvanic corrosion of this material with respect to unalloyed titanium (Ti c.p.) and titanium alloy (Ti-6Al-4V).
  The materials and manufacturing methods used for the subject device are identical to those used in the previously cleared devices, and so additional biocompatibility testing was not considered to be necessary to support the substantial equivalence of the subject device.

- Sterilization
  Klockner Dental Implant Abutments (II) 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 has been carried out to confirm the sterilization parameters.

- Bench testing
  Fatigue testing, conducted according to ISO 14801 and the *Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*, has been performed considering worst-case conditions. Results obtained show that devices performance is acceptable as per their intended use.

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

Conclusions:
We consider that the intended use, the operation principle and the technological characteristics of Klockner Dental Implant Abutments (II) are equivalent to those of predicate devices, although there is a slight difference in the indications for use statement of the subject device compared to the predicate with respect to implant compatibility. There are minor technological differences between the subject and predicate devices. The results of bench testing support the conclusion that risks associated with these technological changes have been adequately mitigated.
Therefore, substantial equivalence of Klockner Dental Implant Abutments (II) to the predicate devices may be established.