April 24, 2023

SOADCO S.L.
% Melissa Burbage
Senior Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K230103
Trade/Device Name: Klockner Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 27, 2023
Received: January 27, 2023

Dear Melissa Burbage:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230103

Device Name
Klockner Abutments

Indications for Use *(Describe)*

Klockner Abutments are intended for use in dental implants to provide a support structure so that the edentulous or partially edentulous patients will regain their masticatory and aesthetic functions.

All digitally designed abutments for use with Klockner TiBase Abutments are intended to be sent to a SOADCO S.L. validated milling center for manufacture.

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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510(k) Summary

K230103

Klockner Abutments

SOADCO, S.L.

April 24, 2023

ADMINISTRATIVE INFORMATION

Manufacturer Name	SOADCO S.L. Av. del Pessebre, 76-82 AD700 Escaldes - Engordany, Andorra Telephone: +37 (6) 800-590
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DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Klockner Abutments
Common Name	Dental implant abutment
Classification Name	Endosseous dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K151194, Klockner Dental Implant Abutments (II), SOADCO, S.L.

Reference Devices
K170022, Klockner Vega TiBase for CEREC®, SOADCO, S.L.
K222288, DESS Dental Smart Solutions, Terrats Medical SL
K191123, Multi-unit Abutments, Medentika GmbH
K220612, PrimeLOC Attachment System, Innovative Product Brands, Inc.

INDICATIONS FOR USE STATEMENT

Klockner Abutments are intended for use in dental implants to provide a support structure so that the edentulous or partially edentulous patients will regain their masticatory and aesthetic functions.

All digitally designed abutments for use with Klockner TiBase Abutments are intended to be sent to a SOADCO S.L. validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for abutments that are compatible with components from the Klockner Dental Implant Systems cleared in K153098, K082200, K080224, and K010132. The abutments consist of healing abutments, temporary abutments, straight abutments, and an overdenture attachment system that consists of abutments, denture housings, and retention inserts, and TiBase abutments with screws.

The subject device Vega Mimetic® Healing Abutments are designed to be connected to the implant during the healing period between implant placement and final abutment placement. Restorations are not placed on the healing components. The healing components are compatible with the Klockner Vega Implant System. They are offered in coronal diameter of 3.6 mm and with gingival heights of 2.0, 3.0, and 5.0 mm. The healing abutments attach to the dental implant with an integrated apical threaded portion. They are manufactured from titanium alloy and are color anodized to aid in identification.

The subject device Vega Mimetic® Temporary Abutments are straight, prepable abutments designed to retain a temporary cemented prosthesis. They are provided straight only and not intended to provide any angulation correction. They are compatible with the Klockner Vega Implant System. The abutment has a hex connection and attaches to the implant with a separate screw, previously cleared under K153098. The abutments are offered in a prosthetic platform diameter of 3.6 mm and a 7.0 mm post height, with gingival heights of 1.0, 2.0, and 3.0 mm. They are manufactured from titanium alloy and are anodized on a portion of the surface for identification purposes.

The subject device Vega Straight Permanent Abutments are designed for single-unit and multiple-unit cement-retained restorations. The straight abutments are compatible with the Klockner Vega Implant System. They are available in an engaging and a non-engaging connection. The engaging design has a hex connection and attaches to the implant with a separate screw. The non-engaging design has a threaded apical portion. They are offered in a prosthetic platform diameter of 4.2 mm and gingival heights of 1.0, 2.0, and 3.0 mm, with no angulation. They are manufactured from titanium alloy and anodized on a portion of the surface for identification purposes.

The subject device K-LOCK Overdenture Attachment System is compatible with the Klockner Vega and Essential Cone Implant System and consists of abutments, retention inserts, and denture housings for attachment of prostheses to endosseous dental implants. All K-LOCK abutments are made of titanium alloy and have the same coronal ridge retention design that attaches to the overdenture component by an interference (snap) fit. The threaded apical end of the abutment connects to the implant and is specific to each compatible implant system and diameter. The

retention connection is designed to accommodate a path of insertion on implants that are divergent up to 40° (with 20°on each side). K-LOCK abutments are provided with a titanium carbonitride (TiCN) coating and are available in cuff (gingival) heights up to 6 mm, with a minimum implant interface diameter of 3.0 mm. A thin titanium carbonitride (TiCN) coating is applied to the abutments in the area that contacts gingival tissue and in the area that contacts the retention inserts.

Subject device TiBase Abutments are two-piece abutments composed of a bottom titanium component and are designed for fabrication of a patient-specific CAD/CAM zirconia superstructure on which a crown may be placed. The patient-specific CAD/CAM zirconia superstructure is the top-half of the two-piece abutment. They also may be used for support of a crown directly on the abutment. There are two types of TiBase Abutments; TiBases that attach directly to the implant, and TiBases that attach to previously-cleared abutments from the sponsor (similar to a prosthetic coping).

All patient-specific custom abutment fabrication for TiBase Abutments is by prescription on the order of the clinician. Zirconia superstructures for use with the subject device TiBase Abutments will be made at a SOADCO validated milling center under FDA quality system regulations and the material will conform to ISO 13356 *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).* The cement recommended in labeling for bonding of superstructures is Panavia F 5.0 cement by Kuraray Noritake Dental, cleared under K183537.

TiBase Abutments that attached directly to the implant are available in an engaging design and a non-engaging design. TiBase Abutments are made of titanium alloy. The TiBase Abutments are provided in four different designs: MedproTiBase, Mimetic TiBase, EC Essential TiBase, and SK2 Medpro TiBase. The EC Essential TiBase is a line extension from previously cleared TiBases for Cerec (K170022). The MedproTiBase abutments are anodized gold. The Mimetic TiBase abutments are coated with a thin layer of zirconium nitride (ZrN).

The design parameters for the CAD/CAM zirconia superstructure to be used on MedproTiBase Abutments are as follows:

Minimum wall thickness – 0.5 mm
Minimum post height – 4.0 mm[1]
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only

[1] For devices 84 01 36 must be a minimum post height of 5.5 mm

The design parameters for the CAD/CAM zirconia superstructure to be used on Mimetic TiBase Abutments are as follows:

Minimum wall thickness – 0.35 mm
Minimum post height – 4.2 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only

The design parameters for the Sirona Dental CAD/CAM system to be used on EC Essential TiBase Abutments for Cerec® are as follows:

Minimum wall thickness – 0.8 mm
Minimum post height – 5.2 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Maximum angulation of the final abutment – 20°

TiBase Abutments that attached directly to previously-cleared angled abutments (like a coping) from SOADCO S.L. are available in an engaging design and a non-engaging design. These TiBase Abutments have no angulation, but some may be placed on abutments that are angled up to 30°. TiBase Abutments are made of titanium alloy and anodized gold. The TiBase Abutments are provided in three different designs: Permanent Vega Medpro, Essential Cone 25° Medpro, and Essential Cone Multi-Cone Medpro. The differences between these designs are primarily related to the compatible implant system or related to connection to a straight or angled abutment.

The design parameters for the CAD/CAM zirconia superstructure to be used on Medpro TiBase to Abutments are as follows:

Minimum wall thickness – 0.5 mm
Minimum post height – 4.0 mm[1]
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Not intended to provide angulation correction

[1] For devices 84 01 26 and 84 01 27 must be a minimum post height of 5.5 mm

PERFORMANCE DATA

Non-clinical testing data submitted to demonstrate substantial equivalence included:

- Sterilization validation according to ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO 17665-2 *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1* was leveraged from previously cleared submissions K151194 and K170022.
- Biocompatibility testing for Klockner TiBase, straight abutments, healing abutments, temporary abutments, and denture housing subject devices leveraged from K170022 and K151194.
- Biocompatibility testing for TiCN coated K-Lock Abutments and ZrN coated Mimetic Abutments according to ISO 10993-5 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity,* ISO 10993-10 *Biological evaluation of medical devices – Part 10: Tests for skin sensitization* for irritation and sensitization, and ISO 10993-12 *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*.
- Mechanical testing according to ISO 14801 *Dentistry – Implants – Dynamic loading test for endosseous dental implant*s.
- Retention testing was conducted to ensure that retention is maintained throughout the expected use of the product.
- The coating characterization using the methods outlined in FDA Guidance *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous*

Dental Implant Abutments, issued May 12, 2002.

- Non-clinical worst-case MRI review to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the subject device components and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

EQUIVALENCE TO MARKETED DEVICES

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K151194 and reference device K170022. There is difference in terminology used, however the intended use is the same. All abutments are intended to be used with dental implants for support for prosthetic restoration for edentulous or partially edentulous patients. The digitally designed abutments are to be sent to a validated milling center for manufacture.

The subject device consists of various types of abutments; healing abutments, temporary abutments, straight abutments, overdenture attachment system, and TiBase abutments.

The subject device healing abutments, temporary abutments, and straight abutments are identical in design, materials, and technological characteristics to similar abutments cleared in the primary predicate K151194.

The subject device overdenture attachment system consists of abutments, retention inserts and denture housings for resilient attachment of prostheses to endosseous implants. The subject device abutment is substantially equivalent to the abutment of the reference device K220612 in its design, materials, and technological characteristics. It is similar to the reference device K220612 in coronal geometry in that the mechanism for overdenture retention is the same. The ability of the attachment system to accommodate abutment divergence is the same as that of the reference device K220612. The diameters and cuff heights offered are similar to those of the reference device K220612. The subject device is manufactured from titanium alloy and has the external surfaces above the implant/abutment interface modified by application of titanium carbonitride (TiCN) coating, similar to the titanium nitride (TiN) coating of the reference device K220612. As with the reference device K220612, the coating is non-porous, the surface roughness of the machined abutment surface is maintained, and the coating is not applied to enhance tissue attachment to the device.

The subject device TiBase (to implant) abutment is substantially equivalent to the predicate device K170022 and the reference device K222288 in terms of design, materials, and technological characteristics. The subject device Mimetic TiBase abutments have external surfaces above the implant/abutment interface modified by application of zirconium nitride (ZrN) coating, similar to the zirconium nitride (ZrN) coating of the reference device K222288. The superstructure design parameters, including angulation, are similar to those of reference device K222288.

The subject device TiBase to abutment (coping) is substantially equivalent to the reference device K191123 in terms of design, materials, and technological characteristics. The TiBase to abutment does not allow for any additional angulation but can be used on abutments with angulation up to 30°.

The subject device abutments are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* The titanium alloy subject device components are manufactured from identical materials, in the identical facilities using the identical manufacturing processes as used for SOADCO S.L. products cleared previously in K151194 and K170022.

All zirconia superstructures for use with the subject device TiBase Abutments will be made at a SOADCO S.L. validated milling center under FDA quality system regulations. The zirconia is inCoris ZI, cleared under K123664, and conforming to ISO 13356, *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).* The cement recommended in labeling for bonding of superstructures is Panavia F 5.0 cement by Kuraray Noritake Dental, cleared under K183537. The zirconia and cement are the same material that was used in previously cleared products K170022.

Provided at the end of this summary is a table comparing the Indications for Use Statements (IFUS) and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

CONCLUSION

The subject device, the primary predicate device, and reference devices have the same intended use and similar technological characteristics. They encompass a similar range of physical dimensions, are manufactured from the same materials, and are to be sterilized using identical methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	Klockner Abutments SOADCO S.L.	**K151194 Klockner Dental Implant Abutment (II) SOADCO S.L.**	**K170022 Klockner Vega TiBase for CEREC® SOADCO S.L.**	**K222288 DESS Dental Smart Solutions Terrats Medical SL**	**K191123 Multi-unit Abutments Medentika GmbH**	**K220612 PrimeLOC Attachment System Innovative Product Brands, Inc.**
	Klockner Abutments are intended for use in dental implants to provide a support structure so that the edentulous or partially edentulous patients will regain their masticatory and aesthetic functions. All digitally designed abutments for use with Klockner TiBase Abutments are intended to be sent to a SOADCO S.L. validated milling center for manufacture.	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 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.	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture. *For complete Indications for Use statement on OEM Compatibility see 510(k) Summary for K222288 in Section 12*	Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient. Multi-unit Abutments are used for the restoration of the following dental implant systems: *For complete Indications for Use statement on OEM Compatibility see 510(k) Summary for K191123 in Section 12.*	The PrimeLOC Attachment System is designed to facilitate patient removal of a dental prosthesis for use with full arch overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.
Reason for Predicate Device	Not applicable	Healing abutment, temporary abutment, straight abutment	Ti Base, validated milling center	TiBase to implant, 30 degrees	TiBase to abutment (coping)	Attachment system design
Product Codes	NHA	NHA	NHA	NHA	NHA	NHA
Designs/Features						
Abutment Design	Healing, Temporary, Straight, Attachment System, TiBase, TiBase to abutment (coping)	Conventional one-piece abutments	Titanium Base Abutments	Healing, Temporary, Straight, TiBase to implant	TiBase to abutment (coping)	Overdenture Attachment
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Internal Thread
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Multi-unit	Multi-unit

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	Klockner Abutments SOADCO S.L.	**K151194 Klockner Dental Implant Abutment (II) SOADCO S.L.**	**K170022 Klockner Vega TiBase for CEREC® SOADCO S.L.**	**K222288 DESS Dental Smart Solutions Terrats Medical SL**	**K191123 Multi-unit Abutments Medentika GmbH**	**K220612 PrimeLOC Attachment System Innovative Product Brands, Inc.**
Abutment-Implant Platform Diameter (mm)	3.0 – 4.8	3.0 – 4.8	3.0 – 4.8	2.52 – 6.5	3.3 – 5.0	3.5 – 4.1
Prosthetic Platform Diameter (mm)	3.5 – 6.6	3.5 – 6.6	4.5 – 7	4.5 – 6.5	3.3 – 6.5	3.5
Angulation	Up to 30°	0°, 17°, 30°	Up to 20°	Up to 30°	0°, 17°, 30°	0°
Abutment-Implant Interface	Internal, External	Internal	Internal	Internal, External	Internal	Internal
Overdenture Divergence Allowance	20°/40°	n/a	n/a	n/a	n/a	20°/40°
Overdenture Attachment Type	Retention Insert retained in Denture Attachment Housing	n/a	n/a	n/a	n/a	Retention Insert retained in Denture Attachment Housing
Materials						
Abutment Materials	Titanium alloy, ASTM F136 Zirconia, ISO 13356 (copings)	Titanium alloy, ASTM F136	Titanium alloy, ASTM F136 Compatible with the Sirona Dental System inCoris ZI Meso L (K100152 / K111421)	Titanium alloy, ASTM F136 Cobalt-chromium alloy, ASTM F1537 Zirconia, ISO 13356 (copings)	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface Coating (overdenture & Mimetic TiBase)	Titanium Carbonitride, Zirconium nitride	n/a	n/a	Zirconium nitride	n/a	Titanium Nitride
Retention Attachment Component	Nylon	n/a	n/a	n/a	n/a	Nylon