12/29/22

BioClean Dental, LLC
℅ Melissa Burbage
Senior Regulatory Specialist
PaxMed International, LLC
12264 EL Camino Real, Suite 400
San Diego, California 92130

Re: K222984
Trade/Device Name: BioClean Implant Restorative System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 30, 2022
Received: December 1, 2022

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,

Sherrill Lathrop Blitzer

for Andrew 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)*

K222984

Device Name

BioClean Implant Restorative System

Indications for Use *(Describe)*

The BioClean Implant Restorative System is designed to support fixed/detachable partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed/detachable restorations that can be attached with a friction-based engagement system.

All digitally designed copings for use with the BioClean Implant Restorative System are to be sent to BioClean Dental or a validated milling center for manufacture.

The BioClean Implant Restorative System is compatible with the following:

BioClean Implant Restorative System Compatibility	
Implant Components	**Configurations**
Bone Level Straumann® Multi-Unit Abutments NC/RC Straumann Multi-Unit Abutment Occlusal Screw	4.6mm Platform Diameter, All Gingival Heights

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

K222984

BioClean Implant Restorative System

BioClean Dental, LLC

December 29, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	BioClean Dental, LLC 6088 Eagles Nest Drive Jupiter, FL 33458 Telephone: +1 561-373-8238
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Representative/Consultant	Melissa Burbage Kevin A. Thomas, PhD; Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: mburbage@paxmed.com kthomas@paxmed.com; flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	BioClean Implant Restorative System
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
K191123, Multi-unit Abutments, Medentika GmbH

Reference Devices
K213391, High Retention Attachment System, Zest Anchors, LLC
K033699, Locator Bar Attachment System, Zest Anchors, LLC
K142890, Straumann Variobase Abutment, IPS e.max CAD MO Coping, Straumann USA, LLC

INDICATIONS FOR USE STATEMENT

The BioClean Implant Restorative System is designed to support fixed/detachable partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed/detachable restorations that can be attached with a friction-based engagement system.

All digitally designed copings for use with the BioClean Implant Restorative System are to be sent to BioClean Dental or a validated milling center for manufacture.

The BioClean Implant Restorative System is compatible with the following:

BioClean Implant Restorative System Compatibility	
Implant Components	**Configurations**
Bone Level Straumann® Multi-Unit Abutments NC/RC Straumann Multi-Unit Abutment Occlusal Screw	4.6mm Platform Diameter, All Gingival Heights

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for the BioClean Implant Restorative System. The BioClean Implant Restorative System provides rigid connection of partial and full arch restorations to endosseous dental implants in the mandible or maxilla.

The BioClean Implant Restorative System consists of copings, denture housings, and retention inserts that are intended to allow for a fixed/detachable prosthesis to be connected to OEM multi-unit abutments for stable attachment of the prosthesis to endosseous dental implants. All BioClean copings are made of titanium alloy and have the same coronal ridge retention design that attaches to the prosthesis component by a friction-based engagement system. The subject device coping connects to the OEM multi-unit abutment and is specific to each compatible abutment system and diameter.

The subject device copings are offered with angulation from 0° to 9° in 0.5° increments and also in a patient specific version in which the dental laboratory technician designs the coping in CAD software and then sends the design to BioClean Dental or a validated milling center for fabrication from a coping blank. By use of a combination of pre-manufactured and patient-specific versions of the copings, a multi-unit prosthesis can be created in which the copings are parallel.

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*
- Biocompatibility testing according to ISO 10993-5 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* 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
- Reverse engineering to verify OEM compatibility to the OEM abutment-implant system. Key dimensions were measured from OEM implants, abutments and screws, from which dimensions and tolerances were established for corresponding BioClean copings, to ensure that the subject device components are compatible with the corresponding OEM system connections. When determining manufacturing tolerances, suitable adjustments in dimensions to avoid interference at maximum material conditions for the abutment and for the coping are taken into consideration.
- Retention testing was conducted to ensure that retention is maintained throughout the expected use of the product. Retention strength of the subject devices was tested and compared to the retention strength of reference device K033699.
- 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

Indications for Use

The subject device and primary predicate K191123 include indications for partial or full arch restorations, referred to as bridges and bars in the predicate device indications. The slight difference in terminology does not affect the intended use; a bridge is considered a partial restoration and a bar is considered a full arch restoration. Both devices have indications for use with dental implants in the mandible or maxilla. Both devices are compatible with OEM systems.

Reference devices were identified to bridge noted technological or verbiage-based differences between the primary predicate and subject devices. The subject device indications are different from primary predicate K191123 in that the primary predicate device indications do not include "fixed/detachable" restorations. The primary predicate K191123 is only for fixed or "screw retained" restorations; this difference is addressed with reference device K033699. The subject

device indications include the fact that the restoration can be attached with a friction-based engagement system; this difference is addressed with reference device K213391. The subject device also allows for the copings to be digitally designed and manufactured at a validated milling center; this difference is addressed with reference device K142890.

The subject device and reference device K213391 include indications for partial or full arch restorations. Indications for both devices include use with dental implants in the mandible or maxilla for purpose of restoring masticatory function. Indications for both devices include attachment of restorations with a friction-based engagement system; this is referred to as a snap-in system for reference device K213391. The slight difference in terminology does not affect the intended use because a snap-in system is another name for a friction-based engagement system. Both devices are compatible with OEM systems.

The subject device indications are different from those for reference deviceK213391 in that the reference device indications do not contain “fixed/detachable” restorations. The reference device K213391 is only for fixed restorations (meaning that it is not removable by the patient); this difference is addressed with reference device K033699. The subject device allows for the copings to be digitally designed and manufactured at a validated milling center; this difference is addressed with reference deviceK142890.

The subject device and reference device K033699 include indications for partial or full arch restorations, referred to as overdentures or partial dentures in the predicate device. The slight difference in terminology does not affect the intended use because a partial denture is considered a partial restoration and an overdenture is considered a full arch restoration. Both devices have indications for use with dental implants in the mandible or maxilla.

The subject device indications are different from reference device K033699 in that the reference device K033699 indications statement does not contain “fixed/detachable” restorations. However, even though it is not listed in the indications, the reference device K033699 device is intended to be removed by the patient. A fixed/detachable restoration is intended to be removed by the patient for cleaning, whereas a fixed restoration is intended to be removed by the clinician for cleaning. The subject device indications include the attachment of the restoration with a friction-based engagement system. However, even though it is not listed in the indications, the reference device K033699 device is attached with a friction-based system. The subject device also allows for the copings to be digitally designed and manufactured at a validated milling center; this difference is addressed with reference device K142890.

The subject device and reference device K142890 include indications for partial restorations, referred to as bridges in predicate device indications. The slight difference in terminology does not affect the intended use because a bridge is considered a partial restoration. Both devices allow for customized restorations using digitally designed copings. Digitally designed subject device copings are to be sent to BioClean Dental or a validated milling center for manufacture. This is similar to reference device K142890. The subject device states “digitally designed copings” whereas the reference device states “digitally designed copings and/or crowns.” Both devices are attached to the abutment that is used within a customized prosthetic restoration, which does not affect the intended use.

The subject device indications are different from reference device K142890 in that the predicate device indications do not include “fixed/detachable” restorations. The reference device K142890 is only for screw-retained or cement-retained fixed restorations; this difference is addressed with reference device K033699. The subject device has limits on the type of restoration, as it does not include single unit. This difference is addressed in primary predicate K191123, reference device K142890, and reference device K213391.

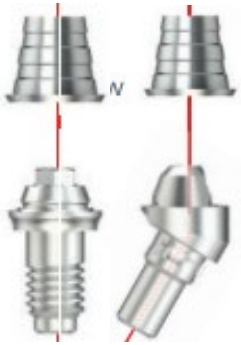
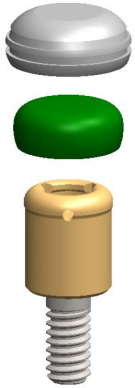
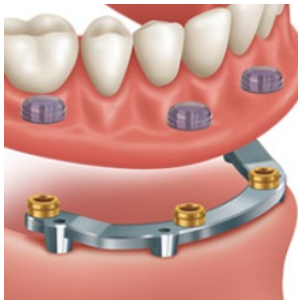
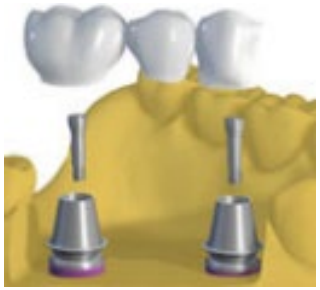
Technological Characteristics

The subject device consists of copings similar to those of the primary predicate K191123 multi-unit titanium base device. Both of these devices attach directly to multi-unit abutments that are angled up to 30°. A difference is that the subject device coping is offered in straight and angled versions up to 9°, whereas the primary predicate K191123 is only offered straight. The total angulation of the assembly does not extend past 30° for either the subject device or primary predicate K191123.

The subject device also consists of retention inserts and denture housings that connect the dental implant/abutment assembly to the restorations by means of a friction-based engagement system (also referred to as snap-in system), similar to the reference device K213391 and reference device K033699. The reference device K213391 is a high retention system that requires the restoration to be removed by the clinician for cleaning (known as a fixed restoration). However, the reference device K033699 has a lower retention strength that allows the patient to remove the restoration for cleaning (known as a fixed/detachable restoration).

The subject device retention insert and denture housing attach to a coping, whereas the reference device K213391 and reference device K033699 device are attached to the abutment. The subject device retention insert and denture housing do not allow for any divergence/convergence, unlike the reference device K213391 and reference device K033699, which allow divergence/ convergence up to 20° per implant or 40° between implants by action of the retention insert and denture housing. The reference device K213391 and reference device K033699 devices are placed on a straight abutment where there is a need for additional angulation correction to allow for the prosthetic restoration connections to be parallel. This additional angulation correction is not needed with the subject devices because they are placed on an angled abutment with an angled coping (with the total not exceeding 30°) in order to obtain a parallel prosthetic restoration connection.

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	BioClean Implant Restorative System BioClean Dental, LLC	K191123 Multi-unit Abutments Medentika GmbH	K213391 High Retention Attachment System Zest Anchors, LLC	K033699 Locator Bar Attachment System Zest Anchors, LLC	K142890 Straumann Variobase Abutment IPS e.max CAD MO Coping Straumann USA, LLC
Indications	The BioClean Implant Restorative System is designed to support fixed/detachable partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed/detachable restorations that can be attached with a friction-based engagement system. All digitally designed copings for use with the BioClean Implant Restorative System are to be sent to BioClean Dental or a validated milling center for manufacture. The BioClean Implant Restorative System is compatible with the following: *For complete Indications for Use statement on OEM Compatibility see Section 4.*	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 High Retention Attachment System is designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed hybrid restorations that can be attached with a snap-in system. The High Retention Attachment System is compatible with the following implants: *For complete Indications for Use statement on OEM Compatibility see 510(k) Summary for K213391 in Section 12.*	The Locator Bar Attachment System is designed for use with overdentures or partial dentures retained in whole or in part by bar splinted endosseous implants in the mandible or maxilla.	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ 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™ Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	BioClean Implant Restorative System BioClean Dental, LLC	K191123 Multi-unit Abutments Medentika GmbH	K213391 High Retention Attachment System Zest Anchors, LLC	K033699 Locator Bar Attachment System Zest Anchors, LLC	K142890 Straumann Variobase Abutment IPS e.max CAD MO Coping Straumann USA, LLC
		 Multi-unit titanium base with multi-unit abutment			 Variobase for Bridge/Bar
Reason for Predicate	n/a	Coping	Friction-based system	Patient removable, retention performance	Patient-specific (CAD/CAM) manufactured at validated milling center
System components	Coping, retention insert, and denture housing *Note: multi-unit abutment and screw are provided by OEM*	Multi-unit abutment, multi-unit titanium base (coping), and screw	Abutment, retention insert, and denture housing	Bar abutment, retention insert, and denture housing	Abutment, coping, crown, and screw
Restoration	Multi-unit	Multi-unit	Multi-unit	Multi-unit	Single and multi-unit
Abutment angulation	0°, 17°, 30°	0°, 17°, 30°	0°	0°	0°
Coping angulation	0 – 9°	0°	n/a	n/a	30°
Divergence allowance (attachment mechanism)	0°	n/a	20° / 40°	20° / 40°	n/a

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	BioClean Implant Restorative System BioClean Dental, LLC	K191123 Multi-unit Abutments Medentika GmbH	K213391 High Retention Attachment System Zest Anchors, LLC	K033699 Locator Bar Attachment System Zest Anchors, LLC	K142890 Straumann Variobase Abutment IPS e.max CAD MO Coping Straumann USA, LLC
Assembly angulation	Up to 30°	Up to 30°	Up to 20°	Up to 20°	Up to 30°
Abutment Platform Diameter	4.6 mm	3.3 – 6.5 mm Multiple systems	2.3 – 7.0 mm Multiple systems	2.3 – 7.0 mm Multiple systems	3.5 – 4.6 mm
Prosthetic attachment mechanism	Nylon Insert retained in Denture Housing	Screw retrained	PEEK Insert retained in Denture Attachment Housing	Nylon Insert retained in Denture Attachment Housing	Screw or cement
Material					
Abutment	n/a	Ti 6Al-4V ELI	Ti 6Al-4V ELI with titanium nitride coating	Ti 6Al-4V ELI or Stainless steel	Ti 6Al-7Nb
Coping	Ti 6Al-4V ELI	Ti 6Al-4V ELI	n/a	n/a	IPS e.max® CAD Ceramic, coron®
Retention inserts	Nylon	n/a	PEEK	Nylon	n/a
Denture housing	Ti 6Al-4V ELI	n/a	Ti 6Al-4V ELI	Ti 6Al-4V ELI	n/a
How provided					
Sterility	Non-sterile	Sterile	Non-sterile	Non-sterile	Non-sterile
Sterilization by end user	Yes	No	Yes	Yes	No
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

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.