June 6, 2022

Innovative Product Brands, Inc.
% Melissa Burbage
Senior Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K220612
Trade/Device Name: PrimeLOC Attachment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 9, 2022
Received: May 9, 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,

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)*

K220612

Device Name

PrimeLOC Attachment System

Indications for Use *(Describe)*

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.

PrimeLOC Attachment Implant Compatibility	
Implant	**Configurations**
Zimmer Biomet Dental Tapered Screw-Vent Implant	3.5mm Platform (3.7mm and 4.1mm body diameters)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K220612

PrimeLOC Attachment System

Innovative Product Brands, Inc.

June 6, 2022

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Device Name	PrimeLOC Attachment 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
K083324, LOCATOR Implant Anchor Attachment System, Zest Anchors, Inc.

Reference Device
K133339, Tapered Screw Vent Implant, Zimmer Dental Inc.

INDICATIONS FOR USE STATEMENT

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.

PrimeLOC Attachment Implant Compatibility	
Implant	**Configurations**
Zimmer Biomet Dental Tapered Screw-Vent Implant	3.5mm Platform (3.7mm and 4.1mm body diameters)

SUBJECT DEVICE DESCRIPTION

The PrimeLOC Attachment System consists of abutments and device-specific accessories (retention inserts and denture housings) to serve in a similar function to LOCATOR® abutments for resilient attachment of prostheses to endosseous dental implants. All PrimeLOC 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 PrimeLOC Attachment System is designed to accommodate a path of insertion divergence of up to 20° per implant and no more than 40° of divergence between implants. PrimeLOC abutments are provided with a titanium nitride (TiN) coating and are available in cuff heights up to 6 mm, with an implant interface diameter of 3.5 mm.

Retention inserts are fixed within a metal denture housing which is embedded in an overdenture prosthesis. The retention inserts allow for varying levels of retention. This connection allows the denture to be retained on the abutments while the majority of loading is supported by the contact of the denture with the gingival tissue surrounding the mandibular and maxillary ridges.

The PrimeLOC Attachment System are compatible with OEM implants, specifically Tapered Screw-Vent 3.5 mm platform dental implants manufactured by Zimmer Dental, Inc. Compatibility is based on agreements with the OEM to ensure that the abutments are designed to fit the corresponding implants. All interfaces of the subject device have been designed and verified by the OEM implant manufacturer. This ensures that the interface of the subject device with the identified compatible implants is appropriate.

A thin titanium nitride coating is applied to the PrimeLOC abutments in the area that contacts gingival tissue and in the area that contacts the retention inserts. The denture attachment housing, which sits within the denture, may be colored through a titanium anodization process.

This system includes instruments used for seating and removing abutments and retention inserts, and processing inserts, impression copings, and laboratory components used to facilitate the fixation of the retention insert and denture housing in the appropriate position within the denture. These components are endosseous dental implant accessories considered Class I 510(k)-exempt devices as defined in 21 CFR 872.3980.

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
- testing of each different type of retention insert in a denture housing to measure removal force from an abutment over multiple sets of insertion/removal cycles compared to the predicate device
- 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

The subject abutment-implant interface of the PrimeLOC Attachment System is verified to be compatible through either OEM signed abutment drawings, OEM implant drawings, and/or established compatibility demonstrated through mutual contractual agreements with the OEM. Once the specifications and tolerances have been identified, the subject device have been designed and verified by the OEM implant manufacturer. This ensures that the interface of the subject device with the identified compatible implants is appropriate.

EQUIVALENCE TO MARKETED DEVICES

The indications for use statement of the subject device is similar to that of the primary predicate device. The subject device has the added text, "designed to facilitate patient removal of a dental prosthesis for use with full arch overdenture…," whereas the primary predicate states, "appropriate for use with overdentures…." This added text only provides more information on how the device is used and does not affect the intended use of the device.

The subject device abutment diameter and abutment cuff height are similar to those of the predicate in that they are within the range of the predicate device. The subject device connection is similar to the internal hex connection of the predicate device, but the subject device is not offered with the additional connections offered by the predicate device. Any differences in technological characteristics were supported by fatigue testing and retention testing to demonstrate substantial equivalence.

Reference Device K133339 is included for the compatible implant body.

Comparison	Subject Device	Primary Predicate Device	Conclusion
	PrimeLOC Attachment Innovative Product Brands, Inc.	K083324 LOCATOR Implant Attachment System Zest Anchors, Inc.	
Indications	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.	The LOCATOR Implant Anchor Abutment for Endosseous Dental Implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.	Similar
Design			
Abutment Diameter, mm	3.5	3.25 to 6.5	Similar
Abutment Cuff Height, mm	1 to 6	0 to 8	Similar
Abutment Angulation	Straight	Straight	Same
Abutment/Implant Interface	Internal Hex	Conical, External Hex, Internal Hex, Internal Multi Lobe	Similar
Divergence Allowance	20°/40°	20°/40°	Same
Prosthesis Attachment Type	Nylon Insert retained in Denture Attachment Housing	Nylon Insert retained in Denture Attachment Housing	Same
Material			
Abutment	Ti 6Al-4V ELI	Ti 6Al-4V ELI	Same
Abutment Coronal Surface Coating	Titanium Nitride	Titanium Nitride	Same
Prosthetic Retention Component	Nylon	Nylon	Same

CONCLUSION

The subject devices and the primary predicate device 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.