August 15, 2023

Implant Logistics, Inc.
℅ Floyd Larson
President
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K231455
Trade/Device Name: Implant-One™ System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: May 16, 2023
Received: May 22, 2023

Dear Floyd Larson:

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)*

K231455

Device Name

Implant-One™ System

Indications for Use *(Describe)*

Implant-One™ System Abutments are intended for use as an aid in prosthetic rehabilitation in the mandible or maxilla for support of single-unit or multi-unit restorations.

The Implant-One Ti-Base Abutment consists of the titanium base and a mesostructure component, making up a two-piece abutment, and will be attached to the implant using an abutment screw. The mesostructure for use with the Implant-One Ti-Base is intended only to be designed and manufactured according to digital dentistry workflow that integrates scan files from lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

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

K231455

Implant-One™ System

Implant Logistics, Inc.

August 9, 2023

ADMINISTRATIVE INFORMATION

Manufacturer Name	Implant Logistics, Inc. 711 Spartan Drive Sparta, WI 54656 Telephone +1 608-498-4855 Fax +1 608-260-7706
Official Contact	Thomas Arendt, President/CEO
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: flarson@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Implant-One™ System
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Secondary Product Code	PNP
Classification Panel	Dental Products Panel
Reviewing Office	OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, Office of Product Evaluation and Quality
Reviewing Division	DHT1B: Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K180899, NobelActive™ Universal Base Abutments, Nobel Biocare USA LLC

Reference Devices
K212394, Implant-One Multi-Unit Abutment, Implant Logistics, Inc.
K102822, Implant-One System, Custom Dental Implants, Inc. (Implant Logistics, Inc.)
K173701, Implant-One System, Implant Logistics, Inc.

INDICATIONS FOR USE STATEMENT

Implant-One™ System Abutments are intended for use as an aid in prosthetic rehabilitation in the mandible or maxilla for support of single-unit or multi-unit restorations.

The Implant-One Ti-Base Abutment consists of the titanium base and a mesostructure component, making up a two-piece abutment, and will be attached to the implant using an abutment screw. The mesostructure for use with the Implant-One Ti-Base is intended only to be designed and manufactured according to digital dentistry workflow that integrates scan files from lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

SUBJECT DEVICE DESCRIPTION

The subject devices comprise abutments designed for the 300, 400, and 500 Series of the Implant-One™ system. All subject device abutments incorporate a Morse taper at the implant/abutment interface, have a hexagonal male end for alignment purposes and are screw retained. The series is grouped according to the implant/abutment interface size and each series is color coded for ease of identification. The subject devices are Titanium Base Abutments.

The Implant-One™ Titanium Base Abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. The Implant-One™ Titanium Base Abutments consist of two major components. Specifically, the titanium base and the mesostructured component make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling.

The standard Ti Base Abutments are offered in cuff heights of 0.5mm, 1.5mm and 2.5mm and have a Ø4.0mm profile for the 300 series and a Ø4.5mm profile for the 400 & 500 series.

The following components are intended to be used for scanning, designing and manufacturing of ceramic mesostructures for the Implant-One™ Titanium Base Abutment:

- Lab scanner: Medit/Identica T500 3D Scanner (Medit Corp)
- CAD software (PNP): 3Shape Abutment Designer & Abutment Design (3Shape A/S – K151455 & K200100) and exocad AbutmentCAD (exocad GmbH – K193352)
- Ceramic material: Katana™ Zirconia (Kuraray Noritake Dental, Inc. – K143439)
- Milling machine: Ceramill Motion 2 (Amann-Girrbach AG)
- Milling software: Ceramill Match 2 CAM Software (Amann Girrbach AG)
- Cement: RelyX™ Luting Plus Automix Cement (3M ESPE Dental Products – K111185)

The design envelope for the ceramic mesostructure of the Ti Base Abutments is shown in Table 1 below.

	Angulation	Thickness, mm	Total height, mm[+]	Margin Diameter, mm	Margin Height, mm (in mesostructure)	Post Height, mm
Min.	0°	0.5	4.75 *	4.0	.25	4.0***
Max	20°	4.5	10.75 **	12.0	3.6	10.0

Table 1 Design Limits in millimeters.

[+]Dimensions from the top of the Implant.
*Includes 0.5 mm minimum cuff height of Ti Base Abutment.
**Includes 2.5 mm maximum cuff height of Ti Base Abutment
*** For single-unit restorations

PERFORMANCE DATA

Non-clinical mechanical testing of the worst-case Implant-One System construct was performed according to ISO 14801 and showed the Implant-One system to be substantially equivalent. Sterilization validations were performed according to ISO 17665-1 and ISO 17665-2. Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the mesostructure component outside of design limitations, including screenshots under user verification testing. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library. No clinical data were used in support of this submission. Support for MR Conditional labeling was leveraged from K212394.

EQUIVALENCE TO MARKETED DEVICES

Implant-One System Dental Abutments are substantially equivalent in Indications for Use to NobelActive™ Universal Base Abutments (K180899). Both are intended for use with endosseous dental implants in the mandible and maxilla to provide prosthetic support.

The Indications for Use Statements (IFUS) for the Implant-One Ti-Base and the primary predicate NobelActive™ Universal Base Abutments indicate the use of the titanium base and a mesostructure component, making up a two-piece abutment, and to be attached to the implant using an abutment screw. The mesostructures for use with both the subject device and the primary predicate device are intended only to be designed and manufactured according to digital dentistry workflow that integrates scan files from intraoral scanners (predicate device) or lab scanners (subject device), CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The subject device is indicated for support of single-unit or multi-unit restorations, while the predicate device's Indications for Use Statement does not specify whether it is for single-unit or multi-unit restorations.

Implant-One Ti-Base abutments are substantially equivalent to NobelActive™ Universal Base Abutments, the primary predicate, in that they have similar ranges of geometries and feature a fixed upper shape with indexing feature that is intended to serve as the platform for an in-laboratory CAD/CAM system made mesostructure. The fixed upper shape and indexing feature facilitates the use of CAD/CAM systems by providing a known shape that can be imported into the design software, thereby simplifying the CAD/CAM design process. Both are retained in the implant with a screw.

The reference devices K102822 and K173701 are in support of implant body compatibilities. Anodization of subject device abutments is supported by biocompatibility testing, leveraged from K212394.

Differences in designs, dimensions or sizes among the subject device and the predicate devices do not affect substantial equivalence.

The subject device is to be sterilized by the end-user, the same as the primary predicate device K180899. Sterilization validation for the subject device was performed according to ISO 17665-1 and ISO TR 17665-2. This sterilization validation method is the same as the primary predicate device K180899.

CONCLUSION

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

Table of Substantial Equivalence – Indications for Use Statement

	Indications for Use Statement
Subject Device	
Implant-One™ System Dental Abutments Implant Logistics, Inc.	Implant-One™ System Abutments are intended for use as an aid in prosthetic rehabilitation in the mandible or maxilla for support of single-unit or multi-unit restorations. The Implant-One Ti-Base Abutment consists of the titanium base and a mesostructure component, making up a two-piece abutment, and will be attached to the implant using an abutment screw. The mesostructure for use with the Implant-One Ti-Base is intended only to be designed and manufactured according to digital dentistry workflow that integrates scan files from lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.
Primary Predicate Device	
K180899 Universal Base Abutment Nobel Biocare AB	The Universal Base Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The Universal Base Abutments consist of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.

Table of Substantial Equivalence – Technological Characteristics

Comparison	**Subject Device**	**Primary Predicate Device**
	Implant-One™ System Dental Abutments Implant Logistics, Inc.	K180899 Universal Base Abutment Nobel Biocare AB
Ti Base abutment		
Product Code	NHA, PNP	NHA, PNP
Emergence profile, mm	4.0, 4.5	4.5
Cuff heights (Ti base), mm	0.5, 1.2, 1.5, 2.5	1.5 and 3.0
Retention	Screw-retained	Screw-retained
Abutment/ Implant Interface	Internal	Internal
Material	Ti-6Al-4V	Ti-6Al-4V
Surface treatment	Color anodization	None
Design of final abutment	Two-piece (Ti Base plus zirconia mesostructure)	Two-piece (Ti Base plus zirconia mesostructure)
Mesostructure Material	Katana Zirconia (K143439)	Enamic Zirconia (K153645)
Maximum Angulation	20°	20°
Recommended Cement	RelyX™ (K111185)	Multilink Hybrid (K130436)
CAD/CAM Workflow Components	Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories	Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.