March 23, 2023

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

Re: K212394
Trade/Device Name: Implant-One™ Multi-Unit Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: February 15, 2023
Received: February 15, 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)*

K212394

Device Name

Implant-One™ Multi-Unit Abutment

Indications for Use *(Describe)*

The Implant-One™ Multi-Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for prosthetic rehabilitation of the mandible or maxilla with a multi-unit restoration.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K212394 – Implant-One™ Multi-Unit Abutment

Implant Logistics, Inc.

March 23, 2023

ADMINISTRATIVE INFORMATION

Manufacturer Name	Implant Logistics, Inc. 711 Spartan Drive Sparta, WI 54656 (608) 498-4855 (Phone) (608) 260-7706 (Fax)
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™ Multi-Unit Abutment
Common Name	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 Division	DHT1B: Division of Dental Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K072570, NobelActive Multi Unit Abutment, Nobel Biocare USA, Incorporated

Reference Device
K173701, Implant-One™ System, Implant Logistics, Inc

INDICATIONS FOR USE STATEMENT

The Implant-One™ Multi-Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for prosthetic rehabilitation of the mandible or maxilla with a multi-unit restoration.

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 Angled Multi-Unit Abutments.

The Implant-One Multi-Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.
The Implant-One Multi-Use Abutments are indicated for multiple-tooth restorations.

Angled Multi-Unit Abutments are available for the 300, 400, and 500 series and used for multiple implant restorations such as screw retained dentures. These abutments are offered in cuff heights of 2.5 mm and 3.5 mm for all series.

PERFORMANCE DATA

Mechanical testing of the worst-case Implant-One System construct was performed according to ISO 14801, leveraged from reference device K173701, and showed the Implant-One Multi-Unit Abutment to be substantially equivalent to the primary predicate device. Sterilization validations performed according to ISO 17665, leveraged from K173701, were relied upon for the subject devices. Biocompatibility data for the subject abutments were leveraged from reference device K173701. No clinical data were used in support of this submission.

A non-clinical worst-case MRI review was conducted to evaluate the Implant-One™ Multi-Unit Abutment in an MRI environment using scientific evidence 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). Titanium alloy (Ti-6Al-4V, ELI) was assessed according to magnetic induction displacement force (ASTM F2052), magnetic induction torque (ASTM F2213), RF induction heating (ASTM F2182), and image artifact (ASTM F2119) by T. O. Woods et al. Based on that rationale, we have addressed parameters per FDA guidance *"Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,"* including magnetic induced displacement force and torque.

EQUIVALENCE TO MARKETED DEVICES

The Implant-One Multi-Unit Abutment is substantially equivalent in Indications for Use to NobelActive Multi Unit Abutment (K072570). All are intended for use with endosseous dental implants in the mandible and maxilla to provide prosthetic support.

The subject device IFUS is essentially identical to that of the primary predicate device NobelActive Multi Unit Abutment except for the product names and the explicit statement in the subject device IFUS that it is intended for rehabilitation with a multi-unit restoration.

Implant-One Multi-Unit Abutment is substantially equivalent to the primary predicate device NobelActive Multi Unit Abutment in that both are made from the same or similar materials and have similar geometries. The subject device is color anodized for color coding, while the NobelActive Multi Unit Abutment is not. However, this difference is not significant to substantial equivalence because it is used only to change the thickness of the naturally occurring oxide layer to provide a perception of color (without dyes or additives) and does not affect the material substrate.

Reference device K173701, Implant-One™ System, is included in support of the substantial equivalence comparison of the subject 30° multi-unit abutment, as K173701 included a single-unit 30° abutment that is leveraged for fatigue strength of the subject abutment.

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

The subject device is to be sterilized by the end-user, the same as the primary predicate device K072570. Sterilization validation for the subject device was performed according to ISO 17665-1 and ISO TR 17665-2, leveraged from prior submissions. This sterilization validation method is the same as that of the primary predicate device K072570.

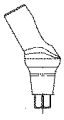
CONCLUSION

The subject device, the primary predicate device, and the reference device have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate and reference devices 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 devices listed above.

Table of Substantial Equivalence – Indications for Use Statement

	Indications for Use Statement
Subject Device	
Implant-One™ Multi-Unit Abutment Implant Logistics, Inc.	The Implant-One™ Multi-Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for prosthetic rehabilitation of the mandible or maxilla with a multi-unit restoration.
Primary Predicate Device	
K072570 NobelActive Multi Unit Abutment Nobel Biocare USA, Incorporated	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for prosthetic rehabilitation.
Reference Device	
K173701 Implant-One™ System Implant Logistics, Inc	The Implant-One™ System is indicated for surgical placement in partially or completely edentulous upper or lower jaws to provide a means for prosthetic attachment to restore a patient's chewing function. The Implant-One™ system is indicated for immediate loading only when primary stability is achieved and with the appropriate occlusal loading.

Table of Substantial Equivalence – Technological Characteristics

Comparison	**Subject Device**	**Primary Predicate Device**	**Reference Device (Leveraged for performance testing)**
	K212394 Implant-One™ Multi-Unit Abutment Implant Logistics, Inc.	K072570 NobelActive Multi Unit Abutment Nobel Biocare USA, Incorporated	K173701 Implant-One™ System Implant Logistics, Inc.
			
Prosthetic platform diameter, mm	4.8	4.8	NA
Cuff heights, mm	2.5, 3.5	1.5, 2.5, 3.5, 4.5	NA
Angulation	17°, 30°	17°, 30°	30° (single-unit abutment used for worst-case mechanical testing)
Mode of retention	Screw-retained	Screw-retained	Cement-retained
Material	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
Surface treatment	Color anodization	None	None