November 29, 2018

Implant Logistics, Inc.
% Karen E. Warden, PhD
President
BackRoads Consulting, Inc.
PO Box 566
Chesterland, Ohio 44026

Re: K173701
Trade/Device Name: Implant-One™ System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 29, 2018
Received: October 30, 2018

Dear Karen E. Warden, PhD:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Implant-One™ System

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary for K173701

Date:	28 November 2018
Sponsor:	Implant Logistics, Inc. 305 3rd Street South Lacrosse, WI 54601 Phone 608-498-4855
Sponsor Contact:	Thomas Arendt
Trade Name:	Implant-One™ System
Common Name:	Dental implant and abutment system
Regulatory Class:	Class II
Primary Classification Name, Regulation, Product Code:	Endosseous dental implant, 21 CFR 872.3640, DZE
Secondary Product Code:	NHA
Submission purpose:	To add new components to the system.
Device Description:	Endosseous implants are self-tapping and threaded, and offered having root-form or wide thread forms. Root-form implant diameters range from 3.25mm to 5.5mm having lengths from 8mm to 14mm. Wide thread implant diameters are available in 4.1 and 4.5mm (8mm to 14mm lengths), 5.5mm (8mm to 12mm lengths) and 6.5mm (8mm to 10mm lengths). Cover screws and healing caps provide protection to the threads of the abutment connection during endosseous and gingival healing. Cover screws are pre- packaged with each implant. Healing caps are provided as an alternative to the cover screw and are packaged separately. The Implant-One™ dental implants and cover screws are provided sterile. Not all abutments can be used for single-unit restorations. The conical, angled conical, ball, locator and glueless abutments are intended only for multi-unit loaded restorations. The ball, locator and glueless abutments are to be used in fully removable dentures. The conical and angled conical abutments are to be used in screw retained dentures and with the titanium sleeve for screw retention. The final design parameters for the custom blank abutment are as follows: maximum total height, 12.5mm; minimum/maximum gingival height, 0.5mm/6mm; minimum post height , 4mm; maximum angulation, 30°; minimum wall thickness, 0.78 (at 1.5mm above the proximal end); minimum diameter, 3.75 mm for the 300 Series, 4.25 mm for the 300 Series and 4.75 mm for the 500 Series.
Indications for Use:	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.
Materials:	All components (implants, abutments, cover screws, healing caps and abutment screws) are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 or wrought titanium alloy (Ti-6Al-4V) as described by ASTM F1472.
Primary Predicate:	Implant-One™ System (Implant Logistics, Inc. – K102822)
Reference Devices:	Ankylos C/X Dental Implant System (Dentsply International – K083805), SynCone Abutment 5° (Dentsply International – K131644), Nobel Active® Multi-unit Abutment (Nobel BioCare® – K072570), Temporary Snap Abutment (Nobel BioCare® – K161435), ArgenIS Titanium Abutment Blanks (The Argen Corporation – K143051), LOCATOR® R-Tx Attachment System (K150295 – Zest Anchors LLC), O-Ring Abutment (K990277 – Biohorizons Implant Systems), MiNi Internal Implant System (K150537 – Megagen Implant Co, Ltd)

Performance Data:

Non-clinical mechanical testing of the worst case Implant-One™ System construct was performed according to ISO 14801 and demonstrated that the Implant-One™ system performs as well as or better than the predicate devices. Biocompatibility testing was performed according to ISO 10993-5 and demonstrated substantial equivalence.

For the modified implant surfaces, the following information was submitted per FDA Guidance, "Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments: identification of the blast media, composition of the particles, identification of the treatments and agents used to remove the particles, a chemical analysis of the surface and SEM photomicrographs of the surface.

Sterilization validations were performed according to ISO 11137 and 17665 and demonstrated substantial equivalence. Packaging and shelf-life validations were performed according to ASTM D4169 including ASTM F1886, ASTM F88 and ASTM F1929 and demonstrated substantial equivalence. The Limulus amebocyte lysate (LAL) test was performed on sterile devices per AAMI ST72 and met the <20EU/Device endotoxin limit.

No clinical data was used in support of this submission.

Technological Characteristics:

The fundamental scientific technology of the Implant-One™ System is the same as previously cleared devices as shown below. Minor differences between the subject and predicate devices did not raise new questions of safety or effectiveness.

Specifically, the minor differences in dimension, surface or connection features between the subject implants, primary predicate and reference device do not introduce new issues of safety or efficacy as demonstrated by the non-clinical mechanical and biocompatibility testing.

Reference devices have been identified to accommodate the dimensional features for the ball, straight, post, wide post, glueless, anatomical angled, solid, custom blank, conical, angled conical, temporary and locator abutments therefore these subject abutments do not introduce new issues of safety or efficacy.

System:	**Implant-One™ 300, 400, 500 series (K173701)**	**Implant-One™ 100, 200 series (K102822)**	**Ankylos C/X Dental Implant (K083805)**	
Material of manufacture:	Titanium and/or titanium alloy	Titanium and/or titanium alloy	Commercially pure titanium	
Design:				
Endosseous implant	Root-form	Root-form	Root-form	
Method of stabilization	Threaded fixation	Threaded fixation	Threaded fixation	
Range of Diameters (mm)	3.5 – 6.5	3.25 – 5.5	3.5 – 5.5	7.0
Range of Lengths (mm)	8 – 14	8 – 14	8 – 17	8 – 14
Modified surface	Yes, resorbable media blasted	Yes, AlO2 blasted	Yes, grit blasted and etched	
Connection to abutment	Hex alignment, 12° included taper, screw attachment or integral screw attachment	Hex alignment, 6° included taper, screw attachment	Keyed alignment, friction-lock taper, thread attachment	

Abutments		Implant-One™ 300, 400, 500 series (K173701)	Implant-One™ 100, 200 series (K102822)	Biohorizons O-Ring Abutment (K990277)
Ball	Surface Treatment	Color anodization, full	None	Color anodization, partial
	Diameter (mm)	4.0, 5.0, 5.5	3.8	3.0, 3.5, 4.5, 5.7
	Collar Height (mm)	2, 3, 4, 5	2, 3, 4, 5	1, 3, 5
	Material	ASTM F136 or F1472	ASTM F1472	Titanium alloy

Abutments		Implant-One™ 300, 400, 500 series (K173701)	Implant-One™ 100, 200 series (K102822)	MiNi Implant System "milling"(K150537)
Straight	Surface Treatment	Color anodization	None	Color anodization
	Diameter (mm)	3.1, 4.1, 4.5mm	4.0mm	3.0, 3.5mm
	Collar Height (mm)	1mm	0.5, 1, 2, 3, 4, 5mm	1.0, 1.5, 2.5, 3.5, 4.5mm
	Material	ASTM F136 or F1472	ASTM F1472	ASTM F136

Abutments		Implant-One™ 300, 400, 500 series (K173701)	Implant-One™ 100, 200 series (K102822)
Post	Surface Treatment	Color anodization	None
	Diameter (mm)	4.0, 5.0, 5.5	4.0
	Collar Height (mm)	0.5, 1, 2, 3, 4, 5	0.5, 1, 2, 3, 4, 5
	Material	ASTM F136 or F1472	ASTM F1472
Wide Post	Surface Treatment	Color anodization	None
	Diameter (mm)	4.0, 5.0, 5.5	4.0
	Collar Height (mm)	0.5, 1, 2, 3, 4, 5	0.5, 1, 2, 3, 4, 5
	Material	ASTM F136 or F1472	ASTM F1472

Abutments		Implant-One™ 300, 400, 500 series	Dentsply International
Glueless	510(k) #	K173701	SynCone 5° (K131644)
	Surface Treatment	Color anodization	None
	Diameter (mm)	4	4
	Collar Height (mm)	0.5	1.5, 3.0, 4.5
	Angulation	0° and 15°	0°, 7.5°, 15°, 22.5°, 30°
	Material	ASTM F136 or F1472	Ti6Al4V ELI

Abutments		**Implant-One™ 300, 400, 500 series**	**Dentsply International**
Anatomical angled	510(k) #	K173701	Ankylos C/X (K083805)
	Surface Treatment	Color anodization	None
	Diameter (mm)	4.0, 5.0, 5.5	5.7
	Collar Height (mm)	0.5, 1, 2, 3, 4, 5	0.75, 1.5, 3.0, 4.5
	Angulation	15° and 30°	7.5°, 15°, 22.5°, 30°, 37.5°
	Material	ASTM F136 or F1472	Titanium
Solid	510(k) #	K173701	Ankylos C/X (K083805)
	Surface Treatment	Color anodization	None
	Diameter (mm)	4.0, 5.0, 5.5	3.3, 4.5
	Collar Height (mm)	0.5, 1, 2, 3, 4, 5	1.5, 3.0, 4.5, 6
	Material	ASTM F136 or F1472	Titanium

Abutments		**Implant-One™, 300, 400, 500 series**	**Nobel BioCare**
Conical	510(k) #	K173701	Nobel Active Multi-unit Abutment (K072570)
	Surface Treatment	Color anodization	None
	Diameter (mm)	4.8	4.8
	Collar Height (mm)	0.5, 1, 2, 3, 4, 5	1.5, 2.5, 3.5, 4.5
	Material	ASTM F136 or F1472	Titanium vanadium alloy
Angled conical	510(k) #	K173701	Nobel Active Multi-unit Abutment (K072570)
	Surface Treatment	Color anodization	None
	Diameter (mm)	4.8	4.8
	Collar Height (mm)	1	1.5, 2.5, 3.5, 4.5
	Angulation	15°	17° and 30°
	Material	ASTM F136 or F1472	Titanium vanadium alloy
Temporary	510(k) #	K173701	Temporary Snap Abutment (K161435)
	Surface Treatment	Color anodization	None
	Diameter (mm)	4.0, 5.0, 5.5	4.0, 4.5, 6.0
	Collar Height (mm)	0.5, 1, 2, 3, 4, 5	1.5, 3.0
	Material	ASTM F136 or F1472	ASTM F136 or F1472

Abutments		**Implant-One™ 300, 400, 500 series (K173701)**	**LOCATOR® R-Tx (K150295)**
Locator®	Surface Treatment	Color anodization	Titanium nitride (TiN) or CarboNitride (TiCN)
	Diameter (mm)	3.9	3.9
	Collar Height (mm)	0.5, 1, 2, 3, 4, 5	1, 2, 3, 4, 5, 6
	Material	ASTM F136 or F1472	Titanium alloy

Abutments		**Implant-One™, 300, 400, 500 series (K173701)**	**ArgenIS Titanium Abutment Blanks (K143051)**
Custom blank	Surface Treatment	None	None
	Total height (mm)	12.5 (max)	12.5 (max)
	Gingival height (mm)	0.5 (min) 6 (max)	0 (min) 6 (max)
	Post height (mm)	4 (min)	4 (min)
	Angulation	30° (max)	30° (max)
	Wall thickness (mm)	0.78 (1.5mm above the proximal end)	0.65 (at abut/implant interface)
	Diameter (mm)	3.75 (min)	3.5 (min)
	Material	ASTM F136 or F1472	ASTM F136
	Mode of retention	Hex alignment, screw	Screw

Conclusion: The Implant-One™ System is substantially equivalent to the predicate devices referenced above.