



Food and Drug Administration
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August 3, 2016

IMMEDIATELOAD S.A.
Mr. Giovanni Canino
Managing Director
Via Lugano 11
Agnò, 6982
SWITZERLAND

Re: K151757

Trade/Device Name: IMMEDIATELOAD Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 24, 2016
Received: June 27, 2016

Dear Mr. Canino:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Tina Kiang -
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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

Indications for Use

510(k) Number (if known)
K151757

Device Name

IMMEDIATELOAD DENTAL IMPLANT SYSTEM

Indications for Use (Describe)

The IMMEDIATELOAD Dental Implant System is intended to be surgically inserted into the jawbone for support and retention of dental prosthesis such as artificial teeth, crowns, bridges and overdenture to restore the aesthetics of the patient and the mastication function.

The IMMEDIATELOAD dental implant system is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The UNIVERSE implants can be used for surgery in two stages or in single stage.

The POWER and SOLUTION implants can be used for surgery in single stage.

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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K151757
510 (K)SUMMARY

SUBMITTER/510(K) HOLDER:

Company Name: IMMEDIATELOAD S.A.
Company Address: Via Lugano 11
6982 Agno - Switzerland
Company Phone: 041- 916001310
Company Fax: 041- 916001310
Company e-mail: qualityassurance@immediateload.com
Contact person: Mr. Giovanni Canino
Managing Director
Date Summary Prepared: August 2, 2016

DEVICE IDENTIFICATION

Trade/Proprietary Name: IMMEDIATELOAD Dental Implant System
Classification Name: Endosseous Dental Implant
Device Class: Class II
Product Code: DZE & NHA
Classification Panel: Dental
Regulation Number: 872.3640

LEGALLY MARKETED PREDICATE DEVICE

Predicate device	510 (k) Holder	510 (k) No.
ANKYLOS C/X IMPLANT SYSTEM*	Dentsply Intl., Inc.	K083805
NobelActive Internal Connection Implant**	Nobel Biocare USA LLC	K071370
Alpha Bio Dental Implant System**	ALPHA-BIO TEC LTD	K063364

* - Primary Predicate

** - Reference Predicate

DEVICE DESCRIPTION

All IMMEDIATELOAD dental implants have a double external thread that looks flattened from the proximal area to the distal area. There are three types of implants: UNIVERSE (conical biphasic), POWER (conical monophasic), and SOLUTION (cylindrical monophasic), available in different diameters and length combinations. All the implants are made of Titanium Grade 4. They are provided sterile and are ready to be implanted.

For each measure, the connection between the biphasic implant and the relative prosthetic component is secured by a locking taper connection and a preformed hexagon and by a retained screw.

The abutments are prosthetic accessories made of Titanium Grade 5; they are used to engage, form and create dentures. In particular, the abutment is designed to be applied on the biphasic implant during the surgical reopening, after osseointegration. The straight abutment IMMEDIATE has a straight axis compared to implant's axis. It has a transmucosal collar height ranging from 1 mm to 4 mm.

The inclined abutment IMMEDIATE has axis inclined of 15° compared to the implant's axis. It has a transmucosal collar height ranging from 1 mm to 3 mm. These abutments are fixed to the UNIVERSE implant via a connection screw. The OTK abutment is straight and contains an internal connection screw. It has a transmucosal collar height from 1 mm to 3 mm. The abutments are provided non-sterile and the connection screw for abutments are all provided non-sterile and are intended to be sterilized before use.

INDICATIONS FOR USE STATEMENT

The IMMEDIATELOAD Dental implant system is intended to be surgically inserted into the jawbone for support and retention of dental prosthesis such as artificial teeth, crowns, bridges and overdenture to restore the aesthetics of the patient and the mastication function.

The IMMEDIATELOAD dental implant system is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

The UNIVERSE implants can be used for surgery in two stages or in single stage.

The POWER and SOLUTION implants can be used for surgery in single stage.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

IMMEDIATELOAD S.A. claims the substantial equivalence of the IMMEDIATELOAD Dental Implant System to the predicate devices, based on the equivalent intended use, fundamental technology, and operation characteristics. Side-by-side comparison between IMMEDIATELOAD Dental Implant System and its predicate devices is included below.

COMPARISON CHART <u>UNIVERSE</u> DENTAL IMPLANTS			
ATTRIBUTE / CHARACTERISTICS	IMMEDIATELOAD DENTAL IMPLANT SYSTEM (Submitted Device)	LEGALLY MARKETED PREDICATE DEVICES OF Dentsply Intl., Inc.	LEGALLY MARKETED PREDICATE DEVICES OF Nobel Biocare USA LLC
510(k) number	K151757	K083805	K071370
Device Name	UNIVERSE	ANKYLOS C/X IMPLANT SYSTEM (Primary)	NobelActive Internal Connection Implant (Reference)
Endosseous Dental Implants	Root-form tapered	Root-form tapered	Root-form tapered
CFR Section	872.3640	872.3640	872.3640
Pro-code	DZE & NHA	DZE	DZE & NHA
Intended / Indications For Use	<p>The IMMEDIATELOAD Dental implant system is intended to be surgically inserted into the jawbone for support and retention of dental prosthesis such as artificial teeth, crowns, bridges and overdenture to restore the aesthetics of the patient and the mastication function.</p> <p>The IMMEDIATELOAD dental implant system is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The UNIVERSE implants can be used for surgery in two stages or in single stage.</p>	<p>The ANKYLOS C/X Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS C/X Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.</p>	<p>Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including: cement-retained, screw-retained, or overdenture restorations and terminal or intermediate abutment support for fixed bridgework</p>
Design-(Implants)	<ul style="list-style-type: none"> • Implant Type: bone Level implant • Connection Type: internal conometric connection • Neck Design: Straight walled neck with circumferential thread provides crestal seal • Body Design: Tapered design enables placement near impinging anatomical structures while maximizing prosthetic table diameter for natural emergence profile 	<ul style="list-style-type: none"> • Implant Type: bone Level implant • Connection Type: internal conometric connection • Neck Design: Straight walled neck with circumferential thread provides crestal seal • Body Design: Tapered design enables placement near impinging anatomical structures while maximizing prosthetic table diameter for natural emergence profile 	<ul style="list-style-type: none"> • Implant Type: bone Level implant • Connection Type: internal conometric connection • Neck Design: Straight walled neck with circumferential thread provides crestal seal • Body Design: Tapered design enables placement near impinging anatomical structures while maximizing prosthetic table diameter for natural emergence profile
Diameter (Implants)	3,4 mm 4,0 mm 5,0 mm	3,5 mm 4,5 mm 5,5 mm 7,0 mm	3,0 mm 3,5 mm 4,3 mm 5,0 mm
Length (Implants)	from 8 to 15 mm	from 8 to 17 mm	from 8,5 to 18 mm
Material (Implants)	Pure titanium, ASTM F67	Pure titanium, ASTM F67	Pure titanium, ASTM F67
Fixture Sterile - (Implants)	Yes	Yes	Yes
Sterilization method	Beta Ray	Gamma Ray	Gamma Ray
Surface Finish (Implants)	double acid etched	Sandblasted and etched	TiUnite Surface treatment

Design -(Abutments)	Healing Abutments, screws, cemented and screwed fixed posts; anchorage posts for removable prostheses with bars or ball attachments. All components are dedicated specifically to UNIVERSE implants and fit to their internal connection and vertical drill hole in a secure and anti-rotational way.	EQUIVALENT Healing Abutments, screws, cemented and screwed fixed posts; anchorage posts for removable prostheses with bars or ball attachments.	EQUIVALENT Healing Abutments, screws, cemented and screwed fixed posts; anchorage posts for removable prostheses with bars or ball attachments.
Materials-(Abutments)	Titanium Ti 6Al 4V ELL, ASTM F136	Pure titanium, ASTM F67	Titanium Ti 6Al 4V ELL, ASTM F136
Inclination (inclined Abutments)	15°	7.5°, 15°, 22.5°, 30°, 37.5°	15°, 17°, 30°
Fixture Sterile - (Abutments)	NO, these parts of the system can be sterilized by the user. Labeling contains instructions for sterilization.	NO. These parts of the system can be sterilized by the user.	NO. These parts of the system can be sterilized by the user.

COMPARISON CHART <u>SOLUTION</u> AND <u>POWER</u> DENTAL IMPLANTS		
ATTRIBUTE / CHARACTERISTICS	IMMEDIATELOAD DENTAL IMPLANT SYSTEM (Submitted Device)	LEGALLY MARKETED PREDICATEDEVICES OF ALPHA-BIO TEC LTD (Reference)
510(k) number	K151757	K063364
Device Name	SOLUTION and POWER	Alpha Bio Dental Implant System
Endosseous Dental Implants	Root-form tapered (cylindrical and conical implant)	Root-form straight & tapered (cylindrical and conical implant)
CFR Section	872.3640	872.3640
Pro-code	DZE	DZE
Intended / Indications For Use	The IMMEDIATELOAD Dental implant system is intended to be surgically inserted into the jawbone for support and retention of dental prosthesis such as artificial teeth, crowns, bridges and overdenture to restore the aesthetics of the patient and the mastication function. The IMMEDIATELOAD dental implant system is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The POWER and SOLUTION implants can be used for surgery in single stage.	The Alpha-Bio Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. The Alpha-Bio Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Design-(Implants)	<ul style="list-style-type: none"> • Implant Type: bone Level implant • Connection Type: Not Applicable • Neck Design: Straight walled neck with circumferential thread provides crestal seal • Body Design: Cylindrical and Tapered design enables placement near impinging anatomical structures while maximizing prosthetic table diameter for natural emergence profile 	<ul style="list-style-type: none"> • Implant Type: bone Level implant • Connection Type: Not Applicable • Neck Design: Straight walled neck with circumferential thread provides crestal seal • Body Design: Tapered design enables placement near impinging anatomical structures while maximizing prosthetic table diameter for natural emergence profile

POWER diameter and length combinations	3,4 mm x 8, 10, 11.5, 13, 15 4,0 mm x 8, 10, 11.5, 13, 15 5,0 mm x 8, 10, 11.5, 13, 15	
SOLUTION Diameter and length combination	3,0mm diameter x 11, 13, and 15mm	
Predicate Implant Diameter	N/A	3,0 mm 3,3 mm 3,6 mm 4,2 mm 5,0 mm
Predicate Implant lengths	N/A	from 8 to 15 mm (not all lengths available for all diameters)
Material (Implants)	Pure titanium, ASTM F67	Titanium alloy Ti 6Al 4V ELI, ASTM F136
Fixture Sterile - (Implants)	Yes	Yes
Sterilization method	Beta Ray	Gamma Ray
Surface Finish (Implants)	double acid etched	TiUnite Surface treatment

PERFORMANCE DATA

IMMEDIATELOAD S.A. has conducted laboratory testing and determined device functionality and conformance to design input requirements. The material used for the IMMEDIATELOAD dental Implant System, as well as the manufacturing methods, are similar to legally marketed devices. Surface treatment used for IMMEDIATELOAD dental Implant System is considered equivalent to the surface treatment method used for the predicate devices.

Non-clinical Testing of the subject device included the following:

- End User Steam Sterilization Test according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010.
- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.
- Fatigue Testing according to ISO 14801:2007

The results regarding the fatigue testing of IMMEDIATELOAD dental implants and the predicate devices were comparable. Therefore, it concluded that the IMMEDIATELOAD dental implants perform as intended. Cytotoxicity testing has demonstrated the biocompatibility of the devices. Sterility validation testing was performed and demonstrated the equivalence of the devices to their predicates.

Implants are all made of Titanium medical grade 4 (commercially named pure titanium), while the abutments are grade 5 Ti4Al6V ELI Titanium.

SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject device and the primary predicate device have slight differences in the language of the Indications for Use Statements; however, these slight differences specifying particular models to single or two-stage surgeries do not change the intended use of the device. The subject device and the predicated devices also have similar technological characteristics, and are made of similar, if not identical materials. The subject device and predicate devices encompass a very similar or the exact same range of physical dimensions, including diameter and length of the implants and diameter, height and angle of the abutments and a comparative surface area.

CONCLUSION

IMMEDIATELOAD S.A. has demonstrated that the IMMEDIATELOAD Dental Implants System is substantially equivalent to the predicate devices in terms of intended use, material composition, fundamental scientific technology, principles of operation, and basic design.

Based on the foregoing, the IMMEDIATELOAD Dental Implants System is substantially equivalent to the legally marketed, claimed predicate devices.