K133613

MAR 2 0 2014

INTRA-LOCK INTERNATIONAL

510(k) SUMMARY

Submitter's Name:	Intra-Lock® International 6560 West Rogers Circle Boca Raton, FL 33487
Phone:	(561) 447-8282
Facsimile:	(561) 447-8283
Contact Person:	Mary L. Jean
Date Prepared:	March 12, 2014
Trade Name:	Intra-Lock® Dental Implants
Common Name:	Dental Implant
Classification Name:	Implant, Endosseous, Root-Form
Classification:	Class II
Regulation Number:	872.3640
Product Code:	DZE
Predicate Devices:	Intra-Lock® Dental Implant System with Blossom, K103194 BioHorizons Internal, Single-Stage and Tapered Implant Systems, K073268, K073282 & K071638
Description:	The Intra-Lock® Dental Implants are titanium screw-type threaded root-form endosseous implants ranging in diameters from 3.75mm - 5.0mm and length from 8mm – 15mm. The implants in this submission include tapered and straight body implants with short and 2mm collars that have horizontal micro-threads and an internal connection to interface with the abutment.
Intended Use:	Intra-Lock® Dental Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.
Substantial Equivalence:	The Intra-Lock® Dental Implants have the same general intended uses, indications, technological characteristics, and principles of operation as the predicate device(s). Both the proposed and predicate implant designs are equivalent; with tapered and straight body and similar size range with equivalent thread designs to meet the varying needs of the dental professionals. The proposed and predicate implant systems have equivalent principals of operation; offering implant design specific drilling sequence in labeling for preparation of the osteotomy.

Technological Characteristics	Intra-Lock Dental Implants	Intra-Lock Dental Implants with Blossom™ K103194	BioHorizons Implants K073268, K073282, K071638
Material	Ti6AL4V & CP Titanium	Ti6AL4V	Ti6AL4V
Prosthetic connection	Internal Connection	Internal Connection	Internal Connection
Diameter	3.75mm, 4.0mm, 4.3mm, 4.75mm & 5.0mm	3.4mm 4.0mm & 6.0mm	3.5mm 3.8mm, 4.0mm, 4.6mm, 5.0mm, 5.8mm & 6.0mm
Lengths	8mm – 15mm	8mm – 15mm	7.0mm – 15mm
Body Design	Straight & Tapered Tissue and bone level collar	Straight & Tapered	Parallel-wall (straight) & Tapered Tissue and bone level collar
Thread Design	Buttress and Square buttress thread design with traditional cutting flutes or Blossom™	Buttress thread design with Blossom™	Square thread design with traditional cutting flutes
Collar Design	Short (bone level) Long, 2mm, (tissue level) with micro-threads	Short (bone level) with micro-threads	Bone level and tissue level with Laser-Lok microgrooves
Principals of operation	surgical drilling sequence provided by Intra-Lock to create the osteotomy prior to placement of implant. Abutment mates with implant's internal connection	surgical drilling sequence provided by Intra-Lock to create the osteotomy prior to placement of implant. Abutment mates with implant's internal connection	surgical drilling sequence provided by Biohorizon to create the osteotomy prior to placement of implant. Abutment mates with implant's internal connection

Clinical / Non-Clinical Data

No new performance testing was conducted.

Mechanical bench testing of two previously identified Intra-Lock Dental Implant System worst-case scenario (i.e. smallest diameter implant / angled abutments), which remains applicable for the implants contained in this submission and was previously reviewed in K103194, April 21, 2011 and/or K111199, August 8, 2011.

Conclusion:

Based on the data within this submission, the Intra-Lock dental implants are substantially equivalent to the predicate dental implants identified. The minor differences between proposed devices and the predicate devices raise no new issues of safety, risk to health or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

Intra-Lock International, Incorporated
Mary L. Jean
Regulatory Affairs Manager
6560 West Rogers Circle, Building #24
Boca Raton, FL 33487

Re: K133613
Trade/Device Name: Intra-Lock® Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: December 18, 2013
Received: December 26, 2013

Dear Ms. Jean:

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.

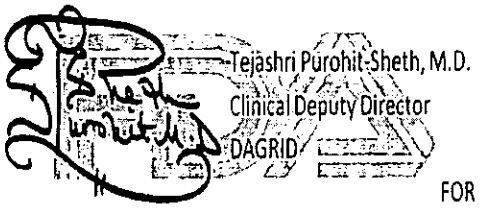
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



FOR

Erin I. Keith, M.S.
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): K133613

Device Name: Intra-Lock® Dental Implants

Indications for Use:

Intra-Lock® Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark S. Runner -S