K103194

510(k) Summary of Safety and Effectiveness

March 7, 2011

APR 2 1 2011

Submitted by: Jeff Sakoff

Address: Intra-Lock International
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Boca Raton, FL 33487

Telephone: 561-447-8282
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Classification Name: Endosseous Dental Implant 21 CFR 872.3640

Trade Name: Intra-Lock Dental Implant System with Blossom

Legally Marketed Device: K021322 Intra-Lock Dental Implant System, K063341 Certain dental implants and K072363 Nanotite dental implants

Device Description: The Intra-Lock Endosseous Dental Implant System with Blossom is a screw-type implant system with a cutting design that incorpoarates at least one cutting surface on each thread. It ranges in diameter from 3.4 to 6mm. The 3.4, 4, and 6mm have a straight body design and there is also a 4mm with a conic body design. The internal connection is a six-spline taperlock design. Abutments include straight, flat top (a wedge shape), o-ball, and 15° & 25° angled (4mm and 6mm only). Prosthetic interface varies with the width of the implant. The 3.4mm has a narrow interface, the 4mms have a standard interface and the 6mm has a wide interface. The angled abutments do not come in narrow interface because of the small diameter of the narrow interface implant.

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

Substantial Equivalence:

	This device.	K021322 Intra-Lock	K072363 Certain	K063341 Certain
Design	Internal six-spline taperlock connection with smaller	Internal six-spline taperlock connection	Internal 12 point hex connection with smaller threading at the top	Internal 12 point hex connection with smaller threading at the top

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	threading at the top			
Sizes	3.4, 4.0, 4.0 conic, 6.0	3.5,3.75,4.0	3.25,3.75,4.0,5.0,6.0	3.25,3.75,4.0,5.0,6.0
Material	Ti 6AL4V	CP Ti	Ti6Al4V	Ti6AL4V
Indication	The Intra-Lock Dental Implant System has 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 prosthesis, from single tooth replacement to full arch reconstruction. They are intended for immediate function on single and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.	The Intra-Lock Implant System has 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 supprt removable or fixed prosthesis, from single toothe replacement to full arch reconstruction.	Intended for surgical placement in the upper or lower jaw to provide the means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing a delayed or immediate loading or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. Intended for immediate function on single tooth and/or multiple tooth applications when good primary stabiliy is achieved, with appropriate occlusal labeling, in order to restore chewing function.	Intended for surgical placement in the upper or lower jaw to provide means for a prosthesis attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. In addition, when a minimum of 4 implants,≥10mm in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated.
Cutting	Blossom	fluted	fluted	fluted

Design				
Testing Results	ISO 14801 fatigue test successful	ISO 14801 fatigue test successful	Unknown, not in 510k summary	Unknown, not in 510k summary

Testing: Fatigue testing according to ISO 14801 was done with both angled abutments in order to demonstrate the design changes did not change the fatigue properties. The fatigue properties of the new design are similar to those of the predicate device.

Substantial Equivalence: The Intra-lock dental implants with Blossom are updated versions of the Intra-lock dental implants. The design, materials, instructions for use and packaging are the same. The indications for use is a combination of the indications for K021322 and K072363. Some of the design changes made to the threading are similar to threading in K063341. Fatigue testing showed this new version of the Intra-lock dental implants with Blossom threads has very similar fatigue properties to the previous version of Intra-lock dental implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Intra-Lock International, Incorporated
C/O Ms. Angela Blackwell
Senior Consultant
Biologics Consulting Group
6560 West Rogers Circle
Boca Raton, Florida 33487

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Re: K103194
Trade/Device Name: Intra-Lock Dental Implant System with Blossom
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 15, 2011
Received: April 18, 2011

Dear Ms. Blackwell:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103194

Device Name: Intra-Lock Dental Implant System with Blossom

Indications for Use:

The Intra-Lock Dental Implant System has been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or maxilla and to support removable or fixed prothesis, from single tooth replacement to full arch reconstruction. They are intended for immediate function on single 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RSBeck DDS for Dr. S. Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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