K080598

MAY 21 2008

Establishment: Intra-Lock International, Inc.
6560 West Rogers Circle
Suite 24
Boca Raton, FL 33487

Proprietary Name: Mini Drive-Lock™ Dental Implant System Prosthetics

Classification Name: Endosseous Dental Implant Abutments (21 CFR 872.3630)

Device Classification: Class II

Predicate Devices:

Predicate Device List		
Product Name	Company	510(k)
Intra-Lock Dental Implant Systems	Intra-Lock International	K021322

Device Description: The Intra-Lock Mini Drive-Lock™ Dental Implant System Prosthetics consist of straight and angled cement retained abutments in various sizes. There are also provisions on the implants for overdenture retention abutment allowing for tissue born or combination tissue and tooth born removable prosthetic appliances. The prosthetics allow for full arch restorations, for either fixed or removable prosthetic appliances. The abutment raw materials consist of Titanium Alloy for Surgical Implant Applications (as per ASTM F 136) Standard Specification for Wrought Titanium-6Aluminium-4Vanadium ELI (Extra Low Interstitial) Alloy. The abutment components are non sterile packaged.

Intended Use: The Intra-Lock Mini Drive Lock™ Implant System Prosthetics have been designed to restore partially or fully edentulous patients. The abutments have been designed to be used in either the mandible or maxilla and to support removable or fixed prosthesis.

Safety and Performance: This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Intra-Lock International has provided information to demonstrate conformity with FDA's guidance document entitled Endosseous Implant Abutments 872-3630. In addition, the FDA Guidance Document for Root Form Endosseous Implants, 872-3640 was also consulted during our preparation of this application for permission to market these products.

Conclusion: Based on the indications for use, technological characteristics, and comparison to predicate devices, the Intra-Lock Mini Drive-Lock™ Implant System Prosthetics have been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2008

Mr. Jeffrey Sakoff
Director of Operations
Intra-Lock International
6560 West Rogers Circle, Suite 24
Boca Raton, Florida 33487

Re: K080598
Trade/Device Name: Mini Drive-Lock™ Dental Implant System Prosthetics
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: February 27, 2008
Received: March 4, 2008

Dear Mr. Sakoff:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
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): K080598

Device Name: Mini Drive-Lock™ Dental Implant System Prosthetics

Indications for Use:

The Intra-Lock Mini Drive Lock™ Implant System Prosthetics have been designed to restore partially or fully edentulous patients. The abutments have been designed to be used in either the mandible or maxilla and to support removable or fixed prosthesis.

Prescription Use ✓ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K080598