K070601

510(k) Summary

OCT 12 2007

Establishment: Intra-Lock International, Inc.
1200 North Federal Highway
Suite 209
Boca Raton, FL 33432

Proprietary Name: Mini Drive-Lock™ Dental Implant System

Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

Device Classification: Class II

Product Name **Company**

510(k)

Predicate Devices:

Product Name	Company	510(k)
Dentatus Monorail™	NATS Corporation	K040143
ERA™ Implant	Sterngold	K021045
Imtec Sendax™ MDI and MDI Plus	Imtec Corporation	K031106

Device Description: The Intra-Lock Mini Drive-Lock™ Dental Implant System consists of machined Titanium, screw-form dental implants, 2.0mm and 2.5mm in diameter and available in lengths of 10mm, 11.5mm, 13mm, 15mm and 18mm. The implant raw material consists of Titanium Alloy for Surgical Implant Applications (as per ASTM F 136 Standard Specification for Wrought Titanium-6Aluminium-4Vanadium ELI (Extra Low Interstitial) Alloy (UNS R56401).
The implants are sterile packaged.

Intended Use: Mini Drive-Lock™ Dental Implants are intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications.

Mini Drive-Lock™ Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants should be used and may be restored after a period of time or placed in immediate function.

Safety and Performance: This submission is a Traditional 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 Implants 872-3640.*

Conclusion: Based on the indications for use, technological characteristics, and comparison to predicate devices, the Intra-Lock Mini Drive-Lock™ Implant System has 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

OCT 12 2007

Mr. Jeffery Sakoff
Director of Operations
Intra-Lock International, Incorporated
1200 North Federal Highway, Suite 209
Boca Raton, Florida 33432

Re: K070601
Trade/Device Name: Mini Drive-Lock™ Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 16, 2007
Received: August 16, 2007

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" (21CFR 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): K070601

Device Name: Mini Drive-Lock™ Dental Implant System

Indications for Use:

3. Mini Drive-Lock™ Dental Implants are intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications.

4. Mini Drive-Lock™ Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants should be used and may be restored after a period of time or placed in immediate function.

Prescription Use X 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: K070601