K050970

OCT 14 2005

510(k) Summary

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

Proprietary Name: Intra-Lock MILO™ Implant

Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

Device Classification: Class II

	Product Name	Company	510(k)
Predicate Devices:	The Maximus™ OS (Overdenture System) Implant	BioHorizons	K041938
	Nobel Direct	Nobel Biocare	K031345
	XiVe® 3.0 Dental Implant System	FRIADENT GmbH	K030639

Device Description: The Intra-Lock MILO™ Dental Implant System consists of machined titanium, screw-form dental implants 3.0mm in diameter. They are available in lengths of 10mm, 11.5mm, 13mm and 15mm. The implants' raw material is 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:

1. MILO™ Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants may be restored after a period of time or placed in immediate function.

MILO™ Implants are indicated for the rehabilitation of single and/or multiple maxillary lateral incisors. They are also indicated for the rehabilitation of single and/or multiple mandibular lateral and/or central and incisors. The implants may be restored after a period of time or placed in immediate function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2005

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

Re: K050970
Trade/Device Name: MILO DENTAL IMPLANT SYSTEM
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 20, 2005
Received: September 20, 2005

Dear Mr. Sakoff:

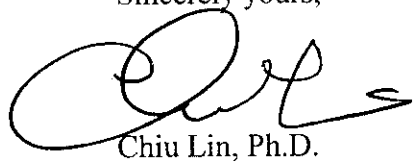
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): K050970

Device Name: MILO™ Dental Implant System

Indications for Use:

1. MILO™ Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants may be restored after a period of time or placed in immediate function.
2. MILO™ Implants are indicated for the rehabilitation of single and/or multiple maxillary lateral incisors. They are also indicated for the rehabilitation of single and/or multiple mandibular central and lateral incisors. The implants 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 C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K050970