K111199

AUG - 8 2011

INTRA-LOCK INTERNATIONAL

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name:	Intra-Lock International 6560 West Rogers Circle Boca Raton, FL 33487
Phone:	(561)447-8282
Facsimile:	(561)447-8283
Contact Person:	Diana Taylor
Date Prepared:	August 4, 2011
Name of Device:	Intra-Lock® 15° Angled Abutment
Common Name:	15° Angled Abutment
Classification Name:	Endosseous Dental Implant Abutment 21 CFR 872.3630
Predicate Devices:	K103194, Intra-Lock Dental Implant System with Blossom
Intended Use/Indications:	Intra-Lock® 15° Angled Abutments are intended for use with Intra-Lock® dental implants to support a prosthetic device in partially or fully edentulous patients. The abutments may be used in single and/or multiple tooth application in the mandible or maxilla.

Technological Characteristics: The subject Intra-Lock® 15° Angled Abutment has a narrow prosthetic interface (SQ Platform) and therefore only mates with implants having SQ Platform. The SQ Platform abutments are anodized a magenta color.

Mechanical Testing: The subject Intra-Lock® 15°Angled Abutment had static and dynamic fatigue testing performed in accordance with ISO 14801:2007 and submitted in this 510(k).

Substantial Equivalence: The subject Intra-Lock® 15°Angled Abutment has the same basic design, and technological characteristics, identical materials, intended use / indications, principles of operation, instructions for use and packaging as the predicate devices in K103194. The minor differences between the subject Intra-Lock® 15°angled abutment and it's predicate(s) raise no new issues of safety or effectiveness. Therefore, the subject Intra-Lock® 15°angled abutment is substantially equivalent to the predicate abutments.

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

AUG - 8 2011

Re: K111199
Trade/Device Name: Intra-Lock® 15° Angled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 28, 2011
Received: July 29, 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

K111199

Indications for Use

510(k) Number: K111199

Device Name: Intra-Lock® 15° Angled Abutment

Indications for Use:

Intra-Lock® 15° Angled Abutments are intended for use with Intra-Lock® dental implants to support a prosthetic device in partially or fully edentulous patients. The abutments may be used in single and/or multiple tooth application in the mandible or maxilla.

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)

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

510(k) Number: K111199