Intra-Lock International, Inc. October 26, 2017

Mary L. Jean
Regulatory Affairs Manager
6560 West Rogers Circle
Bldg. 24
Boca Raton, Florida 33487

Re: K171831
Trade/Device Name: Intra-Lock Bone Fixation System
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: September 21, 2017
Received: September 27, 2017

Dear Mary L. Jean:

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 contact the Division of Industry and Consumer Education (DICE) 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education (DICE) 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,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171831

Device Name
Intra-Lock Bone Fixation System

Indications for Use *(Describe)*
The Intra-Lock Bone Fixation System is indicated for the stabilization and fixation of bone graft, bone filling materials, and/or barrier membranes used to regenerate bone in the oral cavity.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Intra-Lock Bone Fixation System

K171831

1. Submission Sponsor

Intra-Lock International, Inc.

6560 West Rogers Circle

Bldg. 24

Boca Raton

FL 33487

United States of America

Office Phone: (561) 447.8282

Contact: Mary L. Jean

Title: Regulatory Affairs Manager

2. Date Prepared

10/26/17

3. Device Identification

Trade/Proprietary Name:	Intra-Lock Bone Fixation System
Common/Usual Name:	Bone Fixation System
Classification Name:	Intraosseous Fixation Screw or Wire
Regulation Number:	21 CFR 872.4880
Product Code:	DZL
Device Class:	Class II
Classification Panel:	Dental

4. Legally Marketed Predicate Device(s)

K093719, Pro-Fix Precision Fixation System, OSTEOGENICS BIOMEDICAL, INC. (Primary predicate)

K073342, Salvin Dental Specialties Fixation Screw System, Salvin Dental Specialties, Inc. (Reference Device)

K130140, Intra-Lock OP Dental Implant, Intra-Lock International (Reference Device)

K103194, Intra-Lock Dental Implant with Blossom, Intra-Lock International (Reference Device)

5. Indication for Use Statement

The Intra-Lock Bone Fixation System is indicated for the stabilization and fixation of bone graft, bone filling materials, and/or barrier membranes used to regenerate bone in the oral cavity.

6. Device Description

The Intra-Lock Bone Fixation System consists of titanium alloy self-tapping screws, which are tapered and have a minimum diameter of 1.5mm with lengths of 3mm, 4mm, 5mm, 6mm, 7mm, 8mm, 9mm, 10mm and 11mm and a maximum diameter of 2.0mm with lengths of 4mm, 5mm, 6mm, 7mm, 9mm, 11mm, 13mm, and 15mm. Tenting screws are also available in the 1.5 mm diameter. The spacer part of the tenting screws is available in 2mm, 4mm, 6mm, 8mm and 10mm lengths. The screws are manufactured using Ti-6Al-4V alloy (ASTM F-136) and adhere to standards tested under ASTM F-543. This system also includes accessories used to fixate the screws, membranes or bone graft to the host bone including a tapered driver, and a cassette. The screws are designed for removal from the patient after such time when sufficient bone regeneration is demonstrated. The devices are sold non-sterile. Single-use only.

7. Substantial Equivalence Discussion

The following table compares the Intra-Lock Bone Fixation System to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5A – Comparison of Characteristics

Manufacturer	**Intra-Lock International, Inc.**	**OSTEOGENICS BIOMEDICAL, INC.**	**Device Comparison**
Trade Name	**Intra-Lock Bone Fixation System**	**Pro-Fix Precision Fixation System**	
510(k) Number		K093719	
Product Code	DZL	DZL	Same
Regulation Number	21 CFR 872.4880	21 CFR 872.4880	Same
Regulation Name	Intraosseous Fixation Screw or Wire	Intraosseous Fixation Screw or Wire	Same

Manufacturer	**Intra-Lock International, Inc.**	**OSTEOGENICS BIOMEDICAL, INC.**	**Device Comparison**
Trade Name	**Intra-Lock Bone Fixation System**	**Pro-Fix Precision Fixation System**	
Indications for Use	The Intra-Lock Bone Fixation System is indicated for the stabilization and fixation of bone grafts, bone filling materials, and / or barrier membranes used to regenerate bone in the oral cavity.	The Pro-Fix Precision Fixation System is used to stabilize, fixate and/or support bone grafts, bone filling materials and or barrier membranes used for the regeneration of bone in the oral cavity	Same
Mechanism of Action	Self-tapping configuration (MICRO BLOSSOM) incorporates at least one cutting surface on each thread with self-tapping tip. Screw threads enables the implant to continually slice through the bone with increased efficiency and minimal force.	Membrane Fixation screws and Tenting screws are designed with a self-drilling tip allows penetration through cortical bone without the use of a mallet or the need for drilling pilot holes. Bone Fixation screws are designed with finer pitch, self-tapping threads that give the screws greater clamping force while using less driver torque.	Similar
Technology Overview	Self-tapping Square Head Configuration 3mm – 15mm Screw lengths 1.5mm - 2.0mm Screw diameter	Self-drilling Self-tapping Cross Head Configuration 3mm, 8mm, 10mm, 12mm, 14mm Screw lengths 1.5mm Screw diameter	Similar
Anatomical Location	Maxilla or mandible	Maxilla or mandible	Same
Material	Titanium alloy Ti-6Al-4V (ASTM F-136)	Titanium alloy Ti-6Al-4V (ASTM F-136)	Same

Manufacturer	Intra-Lock International, Inc.	OSTEOGENICS BIOMEDICAL, INC.	Device Comparison
Trade Name	**Intra-Lock Bone Fixation System**	**Pro-Fix Precision Fixation System**	
Sterile	Steam Sterilization by End –User	Steam Sterilization by End –User	Same
Single-Use	Yes	Yes	Same
Shelf Life	N/A	N/A	Same
Complies with ISO 10993-1	Yes	Yes	Same

8. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of Intra-Lock Bone Fixation System and in showing substantial equivalence to the predicate devices that are subject to these 510(k) submissions, Intra-Lock Bone Fixation System completed a number of non-clinical performance tests. The Intra-Lock Bone Fixation System meets all the requirements for overall design, sterilization, and biocompatibility results confirming that the design output meets the design inputs and specifications for the device.

Biocompatibility testing per ISO 10993 was not conducted for the Intra-Lock Bone Fixation implant because the materials and manufacturing methods are identical those used in the Intra-Lock OP Dental Implant (K130140) and the anodization process is identical to that used in the Intra-Lock Dental Implant with Blossom (K103194). All Intra-Lock products are manufactured at Intra-Lock Manufacturing. Biocompatibility testing per ISO 10993-1 was not conducted for the Intra-Lock Bone Fixation instruments because their patient contact materials are medical grade 455 and 7-14 stainless steel which is well-known to be biocompatible in the intended applications

The Intra-Lock Bone Fixation System passed all the mechanical testing in accordance with ASTM F543-13 shown below to support substantial equivalence of the subject device:

- Torsion Testing - All tested Unifix screws yielded and fractured whereas the predicate screw head stripped.
- Axial Pullout Testing - No failures of the test specimen were observed. The screw pulled out of the bone foam
- Driving Torque Testing - No failures were observed; the screw pulled from the foam block
- Cleaning and Sterilization Testing - Concluded that the Intra-Lock Bone Fixation System Kit can be steam sterilized to a sterility assurance level of at least 10^{-6} per ISO 17665-1:2006(R)2013.

9. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

10. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The Intra-Lock Bone Fixation System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).