



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

First Ray LLC
Mr. Robert Hoy
Director of Research
124 South 600 West, Suite 100
Logan, Utah 84321

April 8, 2016

Re: K153622
Trade/Device Name: First Ray Internal Bone Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, HWC
Dated: March 21, 2016
Received: March 23, 2016

Dear Mr. Hoy:

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 Parts 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 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" (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 Industry and Consumer Education 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153622

Device Name

First Ray Internal Bone Staple System

Indications for Use (Describe)

The First Ray Internal Bone Staple System is indicated for fixation of bone fractures, fusions, or for bone reconstructions, including:

- Arthrodesis in hand or foot surgery
- Mono or bi-cortical osteotomies in the foot or hand
- Fracture management in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment such as scarf, chevron, etc.

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.

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Internal Bone Staple – Traditional 510(k)

5. 510(k) Summary

Device Trade Name: First Ray Internal Bone Staple System

Manufacturer: First Ray LLC
124 South 600 West, Suite 100
Logan, UT 84321

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Prepared by: Musculoskeletal Clinical Regulatory Advisers, LLC
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Date Prepared: April 7, 2016

Common Name: Staple, Fixation, Bone;
Screw, Fixation, Bone

Classification: 21 CFR 888.3030, 21 CFR 888.3040

Class: II

Product Codes: JDR, HWC

Indications for Use:

The First Ray Internal Bone Staple System is indicated for fixation of bone fractures, fusions or for bone reconstructions, including:

- Arthrodesis in hand or foot surgery
- Mono or bi-cortical osteotomies in the foot or hand
- Fracture management in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment such as scarf, chevron, etc.

Device Description:

The Internal Bone Staple System fixes bone fractures and osteotomies and achieves joint fusion by engaging two bone fragments and holding them together.

Internal Bone Staple – Traditional 510(k)

Predicate Device:

The Richards Staple (pre-amendment), NewDeal Uni-Clip Staple (K011716) and Synthes Cannulated Screw (K963192) serve as the predicate devices.

Technological Characteristics Comparison:

The Internal Bone Staple System and its predicates are similar in design, size and material. Each device is designed to secure bone fragments in close apposition to allow for healing. The Internal Bone Staple System and its predicates are manufactured from titanium alloy conforming to ASTM F136. This is a material with well-established biocompatibility and a long history of use in orthopedic implants. The subject device Bone Screws have the same design and are made of the same material as the predicate screws. The mechanical testing demonstrates that the minor design differences between the Internal Bone Staple and the Richards Staple introduce no new issues of safety or effectiveness.

Nonclinical Testing:

All necessary testing has been performed for the worst-case Internal Bone Staple to assure substantial equivalence to its predicates and demonstrate the subject device performs as intended. All testing was performed on test units representative of finished devices.

The Internal Bone Staple System performance was characterized through static pullout testing in bone analog material and static and fatigue four-point bend testing per ASTM F564-10 (2015) with a side-by-side comparison to the predicate device. Clinical data were not needed to support the safety and effectiveness of the subject device.

Conclusion:

Side-by-side performance testing demonstrates the substantial equivalence of the Internal Bone Staple System to the Richards Staple pre-amendment device. The Internal Bone Staple System is substantially equivalent to the Richards Staple pre-amendment device and NewDeal Uni-Clip Staple (K011716) with respect to its indications for use, material, design, performance and function.