DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 1, 2017

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

Re: K163440
Trade/Device Name: Stealth 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: December 7, 2016
Received: December 8, 2016

Dear Robert 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 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 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 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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)*
K163440

Device Name
Stealth Staple System

Indications for Use *(Describe)*
The Stealth 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.

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

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510(k) Summary

Device Trade Name:	Stealth Staple System
Manufacturer:	First Ray LLC 124 South 600 West, Suite 100 Logan, UT 84321
Contact:	Mr. Robert Hoy Director of Research Phone: (614) 448-6358 Fax: (435) 213-4878 bob@surgicalfrontiers.com
Prepared by:	Musculoskeletal Clinical & Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798
Date Prepared:	January 24, 2017
Common Names:	Staple, Fixation, Bone; Screw, Fixation, Bone
Classifications:	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener
Class:	II
Product Codes:	JDR, HWC

Indications for Use:
The Stealth 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 Stealth Staple System fixes bone fractures and osteotomies and achieves joint fusion by engaging two bone fragments and holding them together.

Predicate Devices:
The Internal Bone Staple System (K153622), marketed as the Stealth Staple System, is the predicate device. The Richards Staple (pre-amendment device), In2Bones, Inc. OS2®-C Compression Staple (K153395) and the Solana Surgical LLC Fuse Force Nitinol Staple (K124045) serve as additional predicates.

Technological Characteristics Comparison:
The Stealth Staple System has the same design and function as its predicate device. The devices consist of two cylindrical staple legs connected by staple bridges. The non-parallel legs are designed to create compression between the fragments when the implant is fully seated. Radial rib features that augment bony purchase are present on the proximal portion of each staple leg. Like the predicate, the Stealth Staple is designed to have no dorsal prominence once inserted. In addition, both the subject and predicate systems contain an optional Cannulated Bone Screw. The Stealth Staple implants are offered in polyetheretherketone (PEEK) as well as the previously cleared titanium alloy. Bone staples with similar indications are manufactured from PEEK and contain the same size ranges as the subject device. There are no substantial differences in technological characteristics between the subject device and predicates. As such, the Stealth Staple System introduces no new issues of safety or effectiveness.

Nonclinical Testing:
The subject device design was evaluated with the following performance tests, using the same methods performed on the predicate device in submission K153622:

- Static Testing
- Fatigue Testing
- Pullout Testing

The results of this testing demonstrate that the Stealth Staple System met the pre-determined acceptance criteria. Therefore, the differences between the subject and predicate devices introduce no new issues of safety or effectiveness.

Conclusion:
The Stealth Staple met all specified criteria performing as intended and did not raise any new issues of safety or effectiveness. The Indications/Intended Use and the fundamental scientific technology of the Stealth Staple System are the same as those described in the predicate device. Based on similarities to its predicate, the Stealth Staple System is substantially equivalent to the predicate Internal Bone Staple System (K152236).