



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

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

April 19, 2016

Re: K153638

Trade/Device Name: Bicortical Fixation Screw & Washer Nut System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: December 17, 2015
Received: December 18, 2015

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)

K153638

Device Name

Bicortical Fixation Screw and Washer Nut System

Indications for Use (Describe)

The Bicortical Fixation Screw & Washer Nut System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

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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Bicortical Fixation Screw & Washer Nut System – Traditional 510(k)

510(k) Summary

Device Trade Name: Bicortical Fixation Screw & Washer Nut 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: April 14, 2016

Common Name: Screw, Fixation, Bone
Washer, Bolt Nut

Classification: 21 CFR 888.3040, 21 CFR 888.3030

Class: II

Product Codes: HWC, HTN

Indications for Use:

The Bicortical Fixation Screw & Washer Nut System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

Device Description:

The Bicortical Fixation Screw & Washer Nut System consists of screws in various diameters and lengths that mate with a washer nut to achieve bicortical fixation.

Predicate Devices:

The Synthes Cortex Screws (K112583) and CrossRoads Screw System (K152072) serve as the predicate devices.

Bicortical Fixation Screw & Washer Nut System – Traditional 510(k)

Predicate Comparison:***Indications***

The subject and predicate devices are indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device. There are no differences in the indications between the subject and predicate devices.

Technological Characteristics

The subject and predicate devices are manufactured from titanium alloy conforming to ASTM F136. This is a material with a long history of biocompatibility and use in previously cleared permanent implants.

Both the subject and predicate constructs are designed to achieve compression of the fracture fragments. In the case of the Bicortical Fixation Screw & Washer Nut, the screw crosses the fracture line, engages with the Washer Nut at the far cortex, and achieves compression of the fracture. In the case of the predicate device, the screw crosses the fracture line, engages with the far cortex, and achieves compression of the fracture. The mechanical testing demonstrates that this minor difference in technology introduces no new issues of safety or effectiveness.

Nonclinical Testing

All necessary testing has been performed for the worst-case Bicortical Fixation Screw & Washer Nut 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 device performance was characterized through torsion and static pullout testing in bone analog material. Clinical data are not needed to support the safety and effectiveness of the subject device.

Conclusion

Side-by-side performance testing demonstrates the substantial equivalence of the Bicortical Fixation Screw & Washer Nut System to the Synthes Cortex Screws. The Bicortical Fixation Screw & Washer Nut System is substantially equivalent to the Synthes Cortex Screws (K112583) and CrossRoads Screw System (K152072) with respect to its indications for use, material, design, and function.