



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

Metric Medical Devices, Incorporated
W. Casey Fox, Ph.D., P.E.
President
846 Silver Springs
Helotes, Texas 78023

January 13, 2016

Re: K152627

Trade/Device Name: IFS Fixation Scaffold System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: December 8, 2015
Received: December 14, 2015

Dear Dr. Fox:

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

Indications For Use

510(k) Number (if Known): K152627

Device Name: Intramedullary Fixation Scaffold (IFS) System

Indications for use: The IFS Fixation Scaffold is indicated for small bone fixation, reconstruction and fusion such as inter-digital fusion of fingers and toes.

Prescription Use X
Use _____
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter

(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)

Appendix I: 510(k) Summary of Safety and Effectiveness

510(k) Summary As required by 21 CFR 807.92:

Name of Sponsor: Metric Medical Devices, Inc., 846 Silver Springs, Helotes, TX, 78023

Contact: W. Casey Fox, Ph.D., P.E., President

Date Prepared: 12/3/2015

Proprietary Name: IFS Fixation Scaffold System

Classification Name: Pin, Fixation, Bone

Device classification: Class II per 21 CFR 888.3040

Product Device Code: HTY

Substantial Equivalence: The IFS is substantially equivalent to legally marketed intramedullary implants (K133520), k-wires (K863734) and bone staple (K123363) in indications for use, material, design and function. Any minor differences between these devices or their performance do not raise any questions of safety and effectiveness.

Indications for use: The IFS Fixation Scaffold is indicated for small bone fixation, reconstruction and fusion such as inter-digital fusion of fingers and toes.

Performance Data: Corrosion susceptibility, implant contraction and expansion forces, ultimate strength, amount of shape change and bone fixation strength was measured and compared between the IFS and three predicate devices.

Corrosion testing per ASTM F2129 "Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices" was performed. The corrosion behavior of the IFS was equivalent or better than the predicate device to which it was compared and presented high corrosion breakdown potentials for all IFS devices tested.

IFS contraction and expansion forces, ultimate strength and bone fixation strength were measured for the IFS and predicate devices. Contraction tests showed that the IFS contraction force causing bone segments to be put into compression was equivalent to or less than the 9x9 mm and 11x10 mm bone staple implants of K123363 and the expansion force causing retention in the medullary canal was equivalent or superior to the K133520 predicate device. Ultimate strength in bending was measured for the IFS, K133520 and K863734 and the IFS was found equivalent or superior in strength to the predicate devices tested. Bone fixation strength was measured for the IFS, K133520 and K863734 and the IFS was found equivalent or superior to the predicate device.

Device Description: The IFS is a hollow fenestrated cylinder fabricated from nitinol with a section that increases the implants diameter to lock into the medullary compartment of bone while shortening its length. The nitinol's transition temperatures are set so that the material is in the austenitic state when released at room temperature. Features on the cylinder's surface, such as bulges and prongs, lock into bone.

The IFS is pre-loaded onto an insertion instrument and held elongated in position by a lock plate. During insertion, the IFS is released by turning a knob on its instrument while the lock plate both releases the IFS and limits the depth of implant insertion.

The IFS implants range in diameter from 2.5 to 4.5 mm and up to 9.3 mm when expanded and range in length from 21 to 27 mm depending on size and extent of contraction.

Comparison of Technical Characteristics with the Predicate Device:

The IFS and predicates K123363 and K133520 are fabricated from nitinol. The IFS and K123363 change shape at room temperature and K133420 changes at body temperature. The IFS and predicate K123363 have essentially the same manufacturing thermal history and surface treatment. The K863734 predicate is fabricated from stainless steel.

The IFS and K123363 both change shape to pull bone together. The IFS shortens its cylindrical length and the K123363 brings its legs together and shortens its bridge to pull bone segments together and apply fixation forces to bone during healing. The fixation force of the IFS is in the same range as a small K123363 implant.

The IFS and K133520 both have sections that expand to lock into the medullary canal of bone. Features on the surface of these devices include barbs or prongs for locking into bone. The expansion force of the IFS is within the range of expansion forces of the predicate K133520.

The IFS and predicate K123363 and K133520 implants are held with an instrument during insertion. The IFS and K123363 instruments are fabricated from the same material. The instruments hold these implants from changing shape. When released from the instrument the shape changing features of the implants are enabled and the bone locking features engage bone. The IFS and K133520 instruments also act as a depth stop.

The K863734 predicate device is implanted with a drill motor, locks due to surface friction and interference, is round in cross section, solid, and has a trocar tip for cutting bone.

The IFS, K133520, K123363 and K863734 are small devices and similar in size: the IFS is 2.5 to 4.5 mm in diameter and up to 9.3 mm when expanded and its length ranges from 21 to 27 mm; the K133520 device ranges in width from 4 mm to 7 mm when expanded and its length ranges 12 to 25 mm; the K123363 device ranges in bridge and leg length from 9 mm to 20 mm; and the K863734 ranges in diameters of 1 mm to 2 mm and lengths exceeding several inches.