DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 11, 2016

Fusion Orthopedics, LLC
% J.D. Webb
Consultant
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K161449
Trade/Device Name: HammerTech® Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 14, 2016
Received: September 20, 2016

Dear J.D. Webb:

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,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K161449

Device Name

HammerTech® Fixation System

Indications for Use *(Describe)*

The HammerTech® device is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

*5*10(k) Summary: HammerTech® Fixation System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	October 3, 2016
Submitted By	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Trade Name	HammerTech® Fixation System
Common Name	Screw, Fixation, Bone
Classification Name	Smooth or threaded metallic bone fixation fastener.
Class	II
Product Code	HWC
CFR Section	21 CFR section 888.3040
Device Panel	Orthopedic
Primary Predicate Device	HammerFiX, Extremity Medical, LLC (K133636)
Secondary Predicate Device	K-wire, Trilliant Surgical (K121008)
Device Description	The HammerTech® Fixation System implant is a polyetheretherketone (PEEK) threaded bone implant intended for fixation of the proximal interphalangeal (PIP) joint of the lesser toes. The PIP implant is comprised of two ends of a single, solid member. Each end slides into the prepared canal of the bone to be fused. The device is a straight cannulated design offered in four different sizes to address the wide variation of patient anatomy.
Materials	Polyetheretherketone (PEEK) (ASTM F2026)
Substantial Equivalence Claimed to Predicate Devices	The HammerTech® Fixation System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The HammerTech® device is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.
Non-clinical Test Summary	The following analyses were conducted: ● Static 4-point bending (ASTM F382) ● Dynamic 4-point bending (ASTM F382) ● Pull-out test (ASTM F543) ● Torsion test (ASTM F543) ● Pyrogenicity was evaluated using the Limulus amebocyte lysate (LAL) assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin level of 20 EU per device.

	The results of these evaluations indicate that the HammerTech® Fixation System is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Fusion Orthopedics, LLC considers the HammerTech® Fixation System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use