November 23, 2018

Fusion Orthopedics, LLC
Authorized Contact Person
4135 S. Power Rd., Suite 110
Mesa, Arizona 85212

Re: K182684
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 20, 2018
Received: September 26, 2018

Dear Fusion Orthopedics, LLC:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

# *5*10(k) Summary: HammerTech™ Fixation System

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

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| **Date Prepared** | November 23, 2018 |
| **Submitted By** | Fusion Orthopedics, LLC<br>4135 S. Power Rd., Suite 110<br>Mesa, AZ 85212<br>800-403-6876 |
| **Primary Contact** | Fusion Orthopedics, LLC<br>4135 S. Power Rd., Suite 110<br>Mesa, AZ 85212<br>800-403-6876 Tele |
| **Trade Name** | HammerTech™ Fixation System |
| **Common Name** | Screw, Fixation, Bone |
| **Class** | II |
| **Product Code** | HWC |
| **CFR Section** | 21 CFR section 888.3040 |
| **Device Panel** | Orthopedic |
| **Primary Predicate Device** | HammerTech™ Fixation System, Fusion Orthopedics (K161449) |
| **Secondary Predicate Device** | PHALINX Hammertoe System, Wright Medical Technology, Incorporated (K150252) K-Wire, Trilliant Surgical (K121008) |
| **Device Description** | The HammerTech Fixation System consists of PEEK (Polyetheretherketone (ASTM F2026)) and titanium alloy (Ti6Al4V ELI (ASTM F136)) threaded bone implants intended for fixation of the interphalangeal joint of the lesser toes. The device is offered in three configurations; straight cannulated PEEK, straight cannulated titanium, and angled solid titanium. Each configuration is offered in five different sizes to address to a variety of patient anatomy. The specialized instruments are made primarily of surgical grade stainless steel (ASTM F899). The implant and associated instrumentation is supplied sterile and non-sterile. |
| **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. |
| **Materials** | Ti-6Al-4V alloy (ASTM F136)<br>Stainless steel (ASTM F899)<br>Polyetheretherketone (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. |

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| **Comparison of Technological Characteristics** | The design of the HammerTech Fixation System is similar in shape to the predicate devices with a proximal threaded portion along with a distal barbed portion. HammerTech implants are fabricated from Polyetheretherketone (PEEK) or titanium alloy whereas the primary predicate is offered in only PEEK. The HammerTech Fixation is offered in smaller sizing than the primary predicate device. The HammerTech Fixation can be steam sterilized or sterile packaged whereas the primary predicate can only be provided sterile packed. |
| **Non-clinical Test Summary** | The following analyses were conducted:<br>• Static 4-point bending (ASTM F382 Annex 1)<br>• Dynamic 4-point bending (ASTM F382 Annex 2)<br>• Pull-out test (ASTM F543 Annex 3)<br>• Torsion test (ASTM F543 Annex 1)<br>• Insertion Torque (ASTM F543 Annex 2)<br>• 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.<br><br>The results of these evaluations indicate that the HammerTech Fixation System is equivalent to the predicate devices. |
| **Clinical Test Summary** | No clinical studies were performed |
| **Conclusions:** | 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, and indications for use. The non-clinical data supports that the HammerTech Fixation System should perform as intended in the specified use conditions and perform comparably to the predicate devices that are currently marketed for the same intended use. |