March 4, 2022

Fusion Orthopedics
Eli Jacobson
Associate Director of Engineering
4135 S Powder Road
Mesa, Arizona 85212

Re: K211843
Trade/Device Name: PolyLock Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 28, 2022
Received: January 31, 2022

Dear Eli Jacobson:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211843

Device Name
PolyLock Plating System

Indications for Use *(Describe)*

The PolyLock System is indicated for use in the treatment of bone fractures, osteotomies, arthrodesis, osteochondritis, and interfragmentary indications in the small bones of the hand, foot, and ankle, including the distal tibia, fibula, talus, and calcaneus. Including, fusions of the forefoot and midfoot, stabilization of 1st, 2nd, 3rd, 4th, and 5th tarsometatarsal fusions, intercuneiform, navicular-cuneiform, talo-navicular, calcaneo-cuboid, and medial column fusions, first metatarsal osteotomies for hallux valgus/rigidus correction, first metatarsal fracture fixation, arthrodesis of the first metatarsal cuneiform joint, and arthrodesis/fusion of the first metatarsophalangeal joint.

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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510(k) Summary: PolyLock Plating System

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

Date Prepared	June 11th, 2021
Submitted By	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876
Primary Contact	Eli Jacobson 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876 Tele e-mail: eli@fusionorthopedics.com
Trade Name	PolyLock Plating System
Common Name	Plate, Fixation, Bone
Class	II
Product Code	HRS, HWC
Regulation	21 CFR Section 888.3030 - Single/multiple component metallic bone fixation appliances and accessories.
Device Panel	Orthopedic
Predicate Devices	Fusion Orthopedics: PolyLock Plating System (K202959) **[Primary Predicate]** Paragon 28: Gorilla Plating System (K203511)
Device Description	The PolyLock Plating System consists of various shapes and sizes of plates for the management of orthopedic osteotomies, reconstruction, and trauma of the foot, ankle, and hand. Features include a low profile, limited contact plate capable of dynamic/manual compression, with threaded screw holes accepting both poly-axial and locking screws. The system also consists of poly-axial and locking screws with diameters consisting of 2.0mm, 2.4mm, 2.7mm, 3.5mm and 4.0mm with lengths from 8mm to 60mm. System instrumentation includes: drill bits, countersinks, K-wires, olive wires, depth gauges, reamers, driver shafts, guides, plate benders, clamps, and driver handles to facilitate the placement of the screws. The implants are intended for single use only. Instruments designed for bone removal are intended for single use only, such as: drill bits, countersinks, reamers, K-wires, and olive wires.
Indications for Use	The PolyLock System is indicated for use in the treatment of bone fractures, osteotomies, arthrodesis, osteochondritis, and interfragmentary indications in the small bones of the hand, foot, and ankle, including the distal tibia, fibula, talus, and calcaneus. Including, fusions of the forefoot and midfoot, stabilization of 1st, 2nd, 3rd, 4th, and 5th tarsometatarsal fusions, intercuneiform, navicular-cuneiform, talo-navicular, calcaneo-cuboid, and medial column fusions, first metatarsal osteotomies for hallux valgus/rigidus correction, first metatarsal fracture fixation, arthrodesis of the first metatarsal cuneiform joint, and arthrodesis/fusion of the first metatarsophalangeal joint.
Materials	Ti-6Al-4V (ASTM F136) Stainless Steel (ASTM F899)

Comparison of Technological Characteristics	The PolyLock Plating System and the predicate plating systems implants are manufactured from titanium alloy (ASTM F136), are compatible with similar sized screws, have similar widths, thickness, lengths and designs/shapes.
Non-clinical Test Summary	Validations were performed on the cleaning, packaging and sterilization of the implants and associated surgical instruments. Engineering rational was performed to show substantial performance equivalence. The results of the testing demonstrate that the device is substantially equivalent to the predicate device identified above.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non- clinical and Clinical	Fusion Orthopedics LLC considers the PolyLock Plating 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.