Fusion Orthopedics, LLC
% J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

October 15, 2018

Re: K181815
Trade/Device Name: DynaBridge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: September 14, 2018
Received: September 17, 2018

Dear Mr. 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. 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,

Daniel S. Ramsey -S
2018.10.15 14:54:22 -04'00'

For 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181815

Device Name

DynaBridge

Indications for Use *(Describe)*

DynaBridge is indicated for:

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
- Fixation of small bone fragments (i.e. Small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: DynaBridge

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

Date Prepared	September 25, 2018
Submitted By:	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-8876
Primary Contact:	J.D. Webb 1001 Oakwood Blvd. Round Rock, TX 78681 512-388-0199 Tele email: jdwebb@orthomedix.net
Trade Name:	DynaBridge
Common Name:	Bone Staple
Classification Name:	Staple, Fixation, Bone
Class:	II
Product Code:	JDR
CFR Section:	21CFR section 888.3030
Device Panel:	Orthopedic
Primary Predicate Devices:	Speed Staple, BioMedical Enterprises, Inc. (K142292)
Secondary Predicate Devices:	Sniper Staple System, Trilliant Surgical (K1623545/ K172405)
Device Description:	The DynaBridge Superelastic Nitinol Implant is a Nickel-Titanium alloy (Nitinol) bone implant intended primarily for fixation of fractured, osteotomy, and arthrodesis of the hand, foot, and bone appropriate for the size of the device. The implant is offered in a range of sizes to address a variety of indications and patient anatomy with bridge sizes from 9mm to 25mm. The system is offered sterile and non-sterile.
Indications for Use:	The DynaBridge is indicated for: • Fracture and osteotomy fixation and joint arthrodesis of the hand and foot. • Fixation of proximal tibial metaphysis osteotomy. • Hand and foot bone fragment and osteotomy fixation and joint arthrodesis. • Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula, and tibia in the lower extremities; the humerus, ulna, or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula, and sternum.

Materials:	Nitinol (ASTM F-2063) Stainless steel (ASTM F899) 6061 Aluminum (ASTM B209)
Substantial Equivalence Claimed to Predicate Devices:	The DynaBridge is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Non-clinical Test Summary:	The following analyses were conducted: • Static Four-Point Bend Test. • Dynamic Four-Point Bend Test. • Pull-out Test. • Corrosion Test. • AI Temperature Test. • 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 DynaBridge Staple is equivalent to predicate devices.
Clinical Test Summary:	No clinical studies were performed.
Conclusions: Non-clinical and Clinical	Fusion Orthopedics, LLC considers the DynaBridge to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principals of operation, technology, materials, and indications for use.