



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Arthrex, Inc.
%Howard Schrayer
Mx Orthopedics, Corp.
1050 Waltham Street, Suite 510
Lexington, Massachusetts 02421

July 20, 2017

Re: K170326

Trade/Device Name: dynaM \ddot{X} TM Intramedullary Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: June 20, 2017
Received: June 21, 2017

Dear Mr. Schrayer:

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 Part 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" (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 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

INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)

K170326

Device Name

dynaMX™ Intramedullary Fixation Device

Indications for Use (Describe)

The dynaMX™ Intramedullary Fixation Device is indicated to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges.

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 OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)**

General Company Information

Name: Arthrex, Inc.
Originally, MXX Orthopedics, Corp.
Contact: Howard Schrayer
Regulatory Affairs Consultant
Address: 1050 Waltham St. Suite 510
Lexington, MA 02421
Telephone: (617) 270 – 6608

Date Prepared April 24, 2017

General Device Information

Product Name: dynaMXX™ Intramedullary Implant
Classification: “Bone Fixation Fastners”
Product code: HTY - Class II
21 CFR 888.3040

Predicate Device

DePuy (Primary Predicate)	Sterile Kirschner Wires and Steinmann Pins [510(k) Number K960385]
OrthoHelix	Intraosseous Fixation System [510(k) Number K120165]
Wright Medical	PRO-TOE® Hammertoe Fixation System [510(k) Number K140148]
BioMedical Enterprises	HammerLock® 2 [510(k) Number K133520]
Memometal Technologies	Smart Toe and X-Fuse [510(k) Number K070598]

Description

The dynaM \ddot{X} TM Intramedullary Implant is intended to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges.

- The implant is fully cannulated with threads on the distal side and two barbs on the proximal side. The implant is offered in multiple combinations of diameter and length to accommodate various anatomies.
- The dynaM \ddot{X} TM Intramedullary Implant is made of biocompatible Nitinol. The barbs of the implant are designed to exhibit superelastic properties at room and body temperature.
- As manufactured, one end of the implant has a screw thread, and the other end a pair of barbs. The screw thread is inserted into a drilled hole in the middle phalange. The barbed end is implanted into a broached canal in the proximal phalange. While inserting the barbed end of the implant, the barbs deflect inward to allow the implant to pass through the broached canal. Once inside the canal, the barbs superelastically return to their flared outward configuration to securely hold the implant in the bone.
- The dynaM \ddot{X} TM Intramedullary Implant is sold as part of a single use disposable kit. The kit includes an implant, pre-loaded onto a delivery device, a drill bit, a broach and a guide wire.

Indications for Use

The dynaM \ddot{X} TM Intramedullary Implant is intended to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges.

Substantial Equivalence

A series of laboratory studies (bench tests and cadaver tests) have been conducted to verify the suitability of the dynaM \ddot{X} TM Intramedullary Implant for its intended use, establish Substantial Equivalence with the predicate devices and confirm reproducibility of the packaging.

These tests include:

Elastic Static Bending Testing
Bending Fatigue Testing
Implant Pull-Out Force
Rotational Stability
Corrosion Testing
Transformation Temperature Determination
Package Seal Strength Verification
Shelf Life

The biocompatibility of Nitinol has been well-established. A reference publication that describes the biocompatibility was appended, together with a copy of the shelf-life / stability protocol that has been designed to support expiry dating of up to 36 months.

Endotoxin testing of the dynaM \ddot{X} TM Intramedullary Implant has been conducted to confirm that the implant is non-pyrogenic.

This submission supports the position that the M \ddot{X} Orthopedics dynaM \ddot{X} TM Intramedullary Implant is substantially equivalent to previously cleared devices, including the devices listed above. A number of predicate devices list the same range of clinical uses.

Conclusions

M \ddot{X} Orthopedics, Corp. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the M \ddot{X} Orthopedics dynaM \ddot{X} TM Intramedullary Implant. The materials from which the M \ddot{X} Orthopedics device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.

Device is one-component construction	Device is one-component construction	Device is one-component construction	Device is one-component construction	Device is one-component construction	Device is one-component construction
Device is delivered into pre-drilled and pre-broached channels	No pre-drilling or broaching required	Device is delivered into pre-drilled and pre-broached channels	Device is delivered into pre-drilled and pre-broached channels	Device is delivered into pre-drilled and pre-broached channels	Device is delivered into pre-drilled and pre-broached channels
Repaired toe is straight	Repaired toe is straight	Repaired toe is straight	Repaired toe is straight or 10°	Repaired toe is straight or 10°	Repaired toe is straight or 10°
Device is intended as permanent implant	Device is intended as temporary implant	Device is intended as permanent implant	Device is intended as permanent implant	Device is intended as permanent implant	Device is intended as permanent implant
Device is radiopaque	Device is radiopaque	Device is radiopaque	Device is radiopaque	Device is radiopaque	Device is radiopaque

Differences

Device is fabricated from Nitinol per ASTM F2063-12	Device is fabricated from 316 LVM Stainless Steel	Device is fabricated from stainless steel	Device is fabricated from stainless steel or titanium	Device is fabricated from Nitinol per ASTM F2063-12	Device is fabricated from Nitinol per ASTM F2063-12
Nitinol material provides fixation to repair	Nitinol not used	Nitinol not used	Nitinol not used	Nitinol material provides fixation to repair	Nitinol material provides fixation to repair
Device is provided with single-use, sterile accessory delivery tools	Device provided without accessories	Part of a reusable kit	Part of a reusable kit	Device is provided with single-use, sterile accessory delivery tools	Part of a reusable kit
Implant is available in 13mm, 14mm, and 15mm lengths	Device is available in lengths ranging from 4” to 9”	Implant is available in 12mm, 13mm, and 14mm lengths	Implant is available in 13mm and 16mm lengths.	Implant is available in 17mm to 22mm lengths.	Implant is available in 15mm to 22mm lengths.
Initial proposed shelf-life 6 months following completion of initial shelf-life study	Shelf-life 3 years	Shelf-life 3 years	Shelf-life 3 years	Shelf-life 5 years	Shelf-life 3 years
Device is provided sterile by gamma radiation and stored at room temperature for `single-patient-use	Device is provided sterile or non-sterile.	Device is provided non-sterile.	Device is provided non-sterile.	Device is provided sterile and stored at room temperature for single patient use.	Device is provided sterile and stored cold for single patient use.