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

July 20, 2017

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

Re: K170326
Trade/Device Name: dynaMẌ™ 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.*

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.**

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

**FORM FDA 3881 (8/14)** Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

# 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
# (Per 21 CFR 807.92)

## General Company Information

Name: Arthrex, Inc.
Originally, MẌ 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: dynaMẌ™ 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 dynaMẌ™ 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 dynaMẌ™ 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 dynaMẌ™ 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 dynaMẌ™ 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 dynaMẌ™ 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 dynaMẌ™ Intramedullary Implant has been conducted to confirm that the implant is non-pyrogenic.

This submission supports the position that the MẌ Orthopedics dynaMẌ™ 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**

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

# SUBSTANTIAL EQUIVALENCE INFORMATION

| **MẌ Orthopedics, Corp.** | **DePuy Inc.** | **OrthoHelix** | **Wright Medical** | **BioMedical Enterprises** | **Memometal Technologies** |
|---|---|---|---|---|---|
| dynaMẌ™ Intramedullary Implant | Sterile Kirschner Wires and Steinmann Pins | Intraosseous Fixation System | PRO-TOE® Hammertoe Fixation System | HammerLock® 2 | Smart Toe and X-Fuse |
| 510(k) K170326 | 510(k) K960385 | 510(k) K120165 | 510(k) K140148 | 510(k) K133520 | 510(k) K070598 |
| **Similarities** | | | | | |
| Device is indicated for stabilizing and aiding in the fixation of fractures, fusions, and osteotomies of the phalanges. | Device is indicated for fixation of bone fractures, for bone reconstruction, as guide pins for insertion of other implants. | Device is intended to stabilize and aid in the fixation of fractures, fusions, and osteotomies of the phalanges. | Device is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures. | Device is indicated for small bone reconstruction and fusion such as inter-digital fusion of fingers and toes. | Device is indicated for small bone reconstruction limited to inter-digital fusion of fingers and toes and small bones fusions. |
| Product code: HTY - Class II<br>21 CFR 888.3040 | Product code: HTY and JDW - Class II 21 CFR 888.3040 | Product code: HTY - Class II 21 CFR 888.3040 | Product code: HWC and JDW - Class II 21 CFR 888.3040 | Product code: HTY - Class II 21 CFR 888.3040 | Product code: HTY - Class II 21 CFR 888.3040 |
| Prescription use in OR setting | Prescription use in OR setting | Prescription use in OR setting | Prescription use in OR setting | Prescription use in OR setting | Prescription use in OR setting |
| Implant is barbed on one side, threaded on the other | Device may be threaded or smooth | Implant is barbed on one side, threaded on the other | Implant is barbed on one side, threaded on the other | Implant is barbed on both sides | Implant is barbed on both sides |
| Middle phalange engaged with 4.0 to 4.5mm thread diameter. | Range in diameter from 0.7mm to 4.7mm | Middle phalange engaged with 4.2 to 4.5mm thread diameter | Middle phalange engaged with 4.0mm thread diameter. | Middle phalange engaged with 5.0 to 7.0mm superelastic barbs | Middle phalange engaged with 6.6mm superelastic barbs |
| Proximal phalange engaged with 6.3mm superelastic barbs. | Range in diameter from 0.7mm to 4.7mm | Proximal phalange engaged with 2.2 to 2.9mm barbs. | Proximal phalange engaged with 2.0 to 3.5mm screw threads. | Proximal phalange engaged with 5.0 to 6.0mm barbs. | Proximal phalange engaged with 6.0 to 7.0mm shape memory base.. |
| Polished and chemically passivated | Polished and chemically passivated | Polished and chemically passivated | Polished and chemically passivated | Polished and chemically passivated | Polished and chemically passivated |

| | | | | | |
|---|---|---|---|---|---|
| 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. |