DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 2, 2016

MẌ Orthopedics Corporation
Howard Schrayer
Official Correspondent
1050 Waltham Street, Suite 510
Lexington, Massachusetts 02421

Re: K160427
Trade/Device Name: dynaMẌ™ Nitinol Compression Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 29, 2016
Received: May 2, 2016

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 Parts 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" (21CFR 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 yours,

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)*
K160427

Device Name
dynaMX™ Nitinol Compression Screw

Indications for Use *(Describe)*
The dynaMX™ Nitinol Compression Screw is indicated for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies. Examples include, but are not limited to scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid. The implants are intended for single use only.

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.

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510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

Name: MẌ Orthopedics, Corp.
Contact: Howard Schrayer
Regulatory Affairs Consultant

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Suite 510
Lexington, MA 02421

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Date Prepared May 31, 2016

General Device Information

Product Name: dynaMẌ™ Nitinol Compression Screw

Classification: "Smooth or Threaded Metallic Bone Fixation Fastener"
Product code: HWC - Class II
21 CFR 888.3040

Predicate Device

Synthes (USA) 3.0mm Headless Compression Screw
[510(k) Number K050636]

Description

The dynaMẌ™ Nitinol Compression Screw is a cannulated self-drilling / self-tapping screw with a threaded head which can be countersunk into the bone. The screw is available in a range of lengths from 16mm to 40mm in 2mm increments. The screw is manufactured from biocompatible superelastic Nitinol. The Nitinol is fully transformed at room temperature and requires no external heating.

Screws are shipped pre-elongated (i.e., stretched). An internal retaining pin maintains the screw in the stretched condition. Following implantation of the screw, removal of the internal retaining pin causes the screw to want shorten to its original un-stretched length. This action generates compression across the fracture site.

Indications for Use

The dynaMŸ™ Nitinol Compression Screw is indicated for fixation of intra-articular and extra-articular fractures and non-unions of small bones and small bone fragments; arthrodesis of small joints; bunionectomies and osteotomies. Examples include, but are not limited to scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid. The implants are intended for single use only.

Substantial Equivalence

A series of laboratory studies (bench tests) have been conducted to verify the suitability of the dynaMŸ™ Nitinol Compression Screw for its intended use, establish Substantial Equivalence with the predicate devices and confirm reproducibility of the packaging.

These tests include:

- Torsional (Failure) Properties
- Driving Torque Properties
- Axial Pullout Strength
- Compression Force Properties
- Transformation Temperature Determination
- Corrosion Testing
- Package Seal Strength Verification

The dynaMŸ™ Nitinol Compression Screw is technologically similar to the primary predicate based on the following characteristics.

- Threaded head which can be countersunk into the bone
- Available in lengths of 16 to 40mm in 2mm increments
- Cannulated for use with K-Wire
- Self-drilling and self-tapping
- Distal screw thread length is 40% of total screw length
- Polished and chemically passivated

The dynaMŸ™ Nitinol Compression Screw is fabricated from biocompatible nitinol and the primary predicate is fabricated from stainless steel. The dynaMŸ™ Nitinol Compression Screw is provided sterile by gamma irradiation and the primary predicate is provided non-sterile.

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™ Nitinol Compression Screw. 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.