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

January 26, 2017

MX Orthopedics, Corp.
Howard Schrayer
Regulatory Affairs Consultant
1050 Waltham Street
Suite 510
Lexington, Massachusetts 02421

Re: K161303
Trade/Device Name: dynaMX™ Compression Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 22, 2016
Received: December 23, 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 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 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)*
K161303

Device Name
dynaMX™ Compression Plate

Indications for Use *(Describe)*
The dynaMX™ Compression Plate is indicated for fixation of small bones and small fragments, osteotomies, arthrodeses, replantations, and reconstructions of small bones and small fragments.

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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510(k) SUMMARY
(Per 21 CFR 807.92)

General Company Information

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

Address: 1050 Waltham St. Suite 510
Lexington, MA 02421

Telephone: (617) 207 – 8604
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Date Prepared January 19, 2017

General Device Information

Product Name: dynaMẌ™ Compression Plate

Classification: "Plate, Fixation, Bone"
Product code: HRS - Class II
21 CFR 888.3030

Predicate Device

Synthes (Primary Predicate)	1.5mm Mini Fragment LCP System [510(k) Number K090047]
Newdeal	Newdeal Compression Plate [510(k) Number K070447] Newdeal Compression Plate [510(k) Number K091609]
Wright Medical	Wright Medical Charlotte Compression Plate [510(k) Number K051908]
BioMedical Enterprises	Nitinol Compression Plating System [510(k) Number K143023]

Description

The dynaMŸ™ Compression Plate provides a means of fixation for small bones and small fragments.

- The dynaMŸ™ Compression Plate is made of biocompatible Nitinol. The bridge of the implant is designed to exhibit superelastic properties at room temperature.

Indications for Use

The dynaMŸ™ Compression Plate is intended for fixation of small bones and small fragments, osteotomies, arthrodeses, replantations, and reconstructions of small bones and small fragments.

Substantial Equivalence

A series of laboratory studies (bench tests) have been conducted to verify the suitability of the dynaMŸ™ Compression Plate 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
Cyclic Potentiodynamic Polarization Corrosion Testing
Galvanic Corrosion Testing
Compressive Force Performance
Transformation Temperature Determination
Package Seal Strength Verification

In addition, laboratory testing has been conducted on the locking screws that are to be used with the compression plate. This testing included:

Insertion and Removal Torque
Torsional Strength
Pullout Strength

The biocompatibility of Nitinol has been well-established.

Technological Comparison

The dynaMŸ™ Compression Plate is technologically equivalent to a number of previously cleared devices. One of the cited predicated devices is fabricated from Nitinol. These metal devices are polished and chemically passivated. The size ranges (length, width and screw length) are in the same range as the dimensions of previously cleared devices intended for the same clinical applications. The devices are provided sterile and are supplied together with instruments designed to facilitate implantation. This submission supports the position that the MŸ Orthopedics dynaMŸ™ Compression Plate is substantially equivalent to previously cleared devices, including the ones listed above. A number of predicate devices list the same range of clinical uses.

Conclusions

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