March 4, 2019

Maxxion Medical, LLC / Baumer SA
℅ Larry Petersen
President
Medical Products International
4241 Wildwood Landing
North Charleston, South Carolina 29420

Re: K181843
Trade/Device Name: MLP Special Locking Bone Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 11, 2019
Received: January 23, 2019

Dear Larry Petersen:

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,

Shumaya Ali -S

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)*
K181843

Device Name
MLP Special Locking Bone Plate System

Indications for Use *(Describe)*
The MLP Special Locking Bone Plate System is indicated for use in internal fixation for bone fractures, fusions, osteotomies, pseudoarthroses, and non-unions of the humerus, radius, ulna, tibia, scapula, clavicle, fibula, tarsal, metatarsal and metatarsophalangeal in pediatrics and adult populations.

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.**

Maxxion

[redacted]

# 510(K) SUMMARY

This 510(k) Summary is herewith being submitted in accordance with the requirements of §21 CFR Part 807.92 for the MLP Special Locking Plate System device.

DATE PREPARED: February 26, 2019

## I. Submitter 807.92(a)(1)

**APPLICANT'S NAME AND ADDRESS:**
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FDA Organization Number: 499884

**APPLICANT'S CONTACT PERSON:**
Mr. Larry Petersen
Regulatory Affairs Consultant
4241 Wildwood Landing
North Charleston, SC 29420 USA
Phone: 1-843-832-3232
Email: Larrypetersen7@gmail.com

## II. DEVICE NAME 807.92(a) (2)

Trade Name: MLP Special Locking Bone Plate System

Common Name**:** Single / Multiple component metallic bone fixation appliances, screws and accessories.

**Classification Name:** §21 CFR 888.3030

Single / Multiple component metallic bone fixation appliances and accessories

**Product Codes:** HRS, HWC

## III. Predicate Devices 807.92(a)(3)

Legally marketed devices to which we are claiming "Substantial Equivalence" are the following:

1. **K063460 – Acumed Bone Implant Plate (Primary Predicate)**
2. **K090047 – Synthes US, Bone Implant Plate**
3. **K163293 – In2Bones Colink™ Plating System**
4. **K083286 – OrthoPediatrics PediLoc Locking Plate System**
5. **K011335 – Synthes one-third tubular DCL Plate**

No reference devices were used in this submission.

## IV. Device Description 807.92(a) (4)

The MLP Special Locking Bone Plate System consists of Bone Plates and locking screw components that are intended to be used in various bone fixation procedures.

The MLP Special Locking Bone Plate System consists of bone plates and screws for fractures, fusions, and osteotomies. The bone plates are pre-bent to minimize bending which is done intraoperatively. Instruments are supplied with the implants to aid in the insertion of the plates and screws. All plates and screws are manufactured from titanium (Ti-6Al-4V) in conformance with ASTM F136. Plates and screws are provided non-sterile.

## V. Statement of Indications for Use of the Device 807.92(a)(5)

### Indications for Use

The MLP Special Locking Plate System is indicated for use in internal fixation for bone fractures, fusions, osteotomies, pseudoarthroses, and non-unions of the humerus, radius, ulna, tibia, scapula, clavicle, fibula, tarsal, metatarsal and metatarsophalangeal in pediatrics and adult populations.

## VI. Comparison of Technological Characteristics with the predicate device 807.92(a)(6)

The technological principle of operation of the subject and predicate devices are

fundamentally the same. The indications for use are similar between the subject and predicate devices.

The subject device is made out of titanium as per ASTM F136. The predicates devices use the similar titanium alloy materials per conformance standards, but also offer implants manufactured from stainless steel materials.

Predicates K163293 and K083286 include pediatric indications as does the subject device.

The subject bone plates and screws offer a wide array of various sizes, shapes, thicknesses, curves, and hole configurations. These are all in a similar range to the matching corresponding plates of the predicates.

## VII. PERFORMANCE DATA 807.92(b)

807.92(b) (1) Brief Discussion of Non-Clinical Tests Submitted:

The Non-clinical tests performed and the Recognized Consensus Standards to which the MLP Special Locking Bone Plate System has been tested are specifically the following:

**ASTM F382-17** Static and Dynamic 4-Point Plate Bending Tests (Annex 1, 2 and 3)
*Specification and Test Method for Metallic Bone Plates*

**ASTM F543-17** Screw, Pull-Out tests, Torque tests and Torsion tests
*Specification and Test Methods for Metallic Medical Bone Screws*

The results of these evaluations indicate that the MLP Special Locking Plate System is equivalent to the predicate devices.

Clinical Testing: 807.92(b) (2)

No clinical Testing was conducted for the subject device.

## VIII. CONCLUSIONS 807.92(b) (3)

The appropriate Mechanical and Biocompatibility testing that was completed successfully, and a comparison to the predicate devices, clearly demonstrates that the MLP Special Locking Plate System has the same intended use and similar technological characteristics. The device performs as intended and does not raise any new safety or effectiveness issues, and is therefore substantially equivalent to the predicate devices.