August 3, 2022

Maxxion Medical, LLC
Guilherme Esteves Pontes
Technical Department Analyst
201, South Biscayne Boulevard, Suite 1200
Miami, Florida 33131

Re: K213614
Trade/Device Name: Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: June 27, 2022
Received: July 8, 2022

Dear Guilherme Esteves Pontes:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213614

Device Name
Cannulated Screw and Double Compression Cannulated Screw

Indications for Use *(Describe)*
Cannulated Screw and Double Compression Cannulated Screw are intended for the treatment of fractures, osteotomies, and arthrodesis of bones with the appropriate screw size.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213614

Device Name
Cannulated Compression Taper Screw

Indications for Use *(Describe)*

The Cannulated Compression Taper Screw (2.5-3.0 mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.

The Cannulated Compression Taper Screw (3.5 mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur, and fibula.

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

In accordance with the requirements of §21 CFR 807.92 the following 510(k) summary is provided for Cannulated Screws.

I. Submitter:

Maxxion Medical, LLC
201 South Biscayne Boulevard, Suite 1200
Miami, FL, 33131 USA
Guilherme Esteves Pontes
Technical Department Analyst
Telephone: +55 19 3805-7693
Email: guilherme.estevesp@outlook.com

Date prepared: November 09, 2021

II. Device Name:

Trade Name:	Cannulated Screws.
Common Name:	Bone fixation screws (Primary) and washers.
Classification Name:	Screw, Fixation, Bone / Washer, Bolt Nut
Device Class:	II
Product Codes:	HWC (Primary), HTN.
Regulation Number:	21 CFR §888.3040 (Primary): Smooth or threaded metallic bone fixation fastener; 21 CFR §888.3030: Single/multiple component metallic bone fixation appliances and accessories; Class II.

III. Predicate Devices:

Legally marketed devices to which we are claiming "Substantial Equivalence" are the following:
Arthrex Compression FT Screws (K201132) (Primary predicate device).
APTUS® Cannulated Compression Screw and APTUS® Headed Cannulated Compression Screw (K202589) (Additional predicate device).

IV. Device Description:

Cannulated Screws are implantable medical devices developed for application in osteosynthesis, with the purpose of reducing, compressing, aligning, stabilizing, and fixing different types of fractures, in small, medium, and large bones, of lower and upper limbs, and can be used in isolated form or

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associated with washers. This submission also includes the corresponding washers for Cannulated Screws.

The screws have a hexagonal connection for a wrench and can be found in three different models: Cannulated Screw, Double Compression Cannulated Screw and Cannulated Compression Taper Screw. These devices are found in a variety of diameters to meet the range of anatomies of the patients, are presented in Titanium Alloy according to the standard ASTM F136, being provided in non-sterile condition.

V. Statement of Indications for Use of the Device:

Cannulated Compression Taper Screw

The Cannulated Compression Taper Screw (2.5-3.0 mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.

The Cannulated Compression Taper Screw (3.5 mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur, and fibula.

Cannulated Screw and Double Compression Cannulated Screw

Cannulated Screw and Double Compression Cannulated Screw are intended for the treatment of fractures, osteotomies, and arthrodesis of bones with the appropriate screw size.

VI. Technological Characteristics:

As was established in this submission, the subject Cannulated Screws are substantially equivalent to the predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics, intended use, indications for use, material composition, anatomical region, multiple sizes, and basic design features compared to its predicate devices. Any differences between the Cannulated Screws and the predicate devices are considered minor and do not raise different questions of safety or effectiveness.

VII. Performance Data:

The Non-clinical tests performed and the Recognized Consensus Standards to which the Cannulated Screws have been tested are specifically the following:

- Torsional Properties of Metallic Bone Screws per ASTM F543
- Driving Torque of Medical Bone Screws per ASTM F543

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- Axial Pullout Strength of Medical Bone Screws per ASTM F543
- Chemical and Mechanical Properties per ASTM F136

The test results demonstrate that the subject device presents safety and efficacy in terms of mechanical properties.

VIII. Conclusions:

Based upon the testing and comparison to the predicate devices, the Cannulated Screws have the same technological characteristics, intended use and indications for use. The devices perform as intended and do not raise any new safety or effectiveness issues and is therefore substantially equivalent to the predicate devices.