Maxx Orthopedics Inc.
Priscilla Herpai
Regulatory Manager
2460 General Armistead Ave, Suite 100
Norristown, Pennsylvania 19403

August 23, 2019

Re: K183684
Trade/Device Name: Libertas - Taper Uncemented Femoral Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO
Dated: July 8, 2019
Received: July 26, 2019

Dear Priscilla Herpai:

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,

FOR Vesa Vuniqi
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183684

Device Name
Libertas™ – Taper uncemented femoral stem

Indications for Use *(Describe)*

The Libertas™ Hip Replacement System is intended for use in total hip arthroplasty. Total hip arthroplasty is intended to provide patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to fix and support the components.

Total hip replacement is indicated for the following conditions:
- Non-inflammatory degenerative joint diseases including osteoarthritis, post traumatic arthritis and avascular necrosis.
- Rheumatoid arthritis.
- Congenital hip dysplasia.
- Acute traumatic fracture of the femoral head or neck.
- Certain cases of Ankylosis.
- Dislocation of the hip.
- Correction of functional deformity.
- Revision of failed joint reconstruction or treatment.
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur.

NOTE:
- The Modular Shell, Uncemented Stem and Taper uncemented stem are intended for press-fit, uncemented use only.
- The Cemented stem is intended for cemented 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

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 92.

Applicant
Maxx Orthopedics Inc.
2460 General Armistead Ave
Suite 100, Norristown, PA 19403
USA

Date of Summary: December 27, 2018

Contact Person
Priscilla Herpai
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Alternate Contact:
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Senior Manager – Regulatory Affairs/Quality Assurance
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Device information:

Proprietary Name: Libertas™ – Taper Uncemented Femoral Stem

Common / Usual Name: Hip Joint Prosthesis

Classification name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353

Product Codes: LZO

Device Class: Class II

Predicate Devices

Equivalent device category	Manufacturer	Trade name	510(k)
Predicate device	Biomet Manufacturing Corp., USA	Taperloc® Complete Stems Taperloc® Complete Microplasty System	K120030, K110400, K103755, K101086, K062994, K043537, K921301,

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Equivalent device category	Manufacturer	Trade name	510(k)
Reference Device	Maxx Orthopedics, Inc, USA	Libertas™ – Hip Replacement System	K180973
Reference Device	Meril Healthcare Pvt. Ltd., India	Latitud™ – Hip Replacement System	K172857

Device Description:
Libertas™ Hip Replacement System cleared under K180973 consists of a modular acetabular cup system, femoral heads, femoral stems, and related accessories.

The purpose of this 510(k) is to add Taper uncemented femoral stem under the Libertas™ Hip device family.

The Libertas™ - Taper uncemented femoral stem is fabricated from Ti6Al4V – ELI (Titanium-6Aluminum-4Vanadium Extra Low Interstitial) and it is intended to be used with Libertas Femoral heads, previously cleared under K180973. The proximal portion of stem is coated with commercially pure Titanium with plasma spray method. Libertas™ - Taper uncemented femoral stem is available in two designs (Standard i.e. full profile design and distally reduced design). Each design is available in different sizes with three neck angles (132° Standard, 132° Lateral, and 128° Standard).

Intended use/Indications:
The Libertas™ Hip Replacement System is intended for use in total hip arthroplasty. Total hip arthroplasty is intended to provide patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to fix and support the components.

Total hip replacement is indicated for the following conditions:

- Non-inflammatory degenerative joint diseases including osteoarthritis, post traumatic arthritis and avascular necrosis.
- Rheumatoid arthritis.
- Congenital hip dysplasia.
- Acute traumatic fracture of the femoral head or neck.
- Certain cases of Ankylosis.
- Dislocation of the hip.
- Correction of functional deformity.
- Revision of failed joint reconstruction or treatment.
- Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur.

NOTE:

- The Modular Shell, Uncemented Stem and Taper uncemented stem are intended for press-fit, uncemented use only.
- The Cemented stem is intended for cemented use only.

Comparison of technological characteristics:
The subject device is substantially equivalent to the previously cleared predicate devices based on similarities in intended use and technological characteristics, materials, and sterilization method.

Non clinical Performance data:
Non-clinical testing was conducted to evaluate device function/mechanical performance and to demonstrate substantial equivalence.

- Proximal fatigue test (ISO 7206-6:2013)
- Distal fatigue test (ISO 7206-4:2010)
- Range of motion test (ISO 21535-2007/Amd 1:2016)
- Axial pull-off test (ISO 7206-10:2003)
- Fretting corrosion (ASTM F1875-98; Reapproved 2014)
- Evaluation of Ceramic femoral head includes Burst test, Fatigue test, Post fatigue burst test, Pull-off test (ISO 7206-10:2003) and Torque test (ASTM F1820-13) (Biolox® delta Modular femoral head and Uncemented Stem)
- Ti coating adhesion (shear) test (ASTM F1044-05; Reapproved 2017)e1

  ASTM F2003-15, ISO 5834-3 and ISO 5834-2)

Endotoxin testing has demonstrated that the manufacturing process does not introduce Endotoxin as a bi-product of the manufacturing and cleaning process.

Conclusion
Based on performance testing results and similarities in intended use, device design/technological characteristics, material, and sterilization method, the Libertas^{TM} - Taper uncemented femoral stem is considered substantially equivalent to the previously cleared predicate device.