Maxx Orthopedics, Inc
% Hollace Rhodes
Senior Director
Musculoskeletal Clinical Regulatory Advisors, LLC
1050 K Street NW
Suite 1000
Washington, District of Columbia 20001

September 28, 2018

Re: K180973
Trade/Device Name: Libertas Hip Replacement System
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDI, LZO
Dated: August 27, 2018
Received: August 28, 2018

Dear Ms. Rhodes:

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,

Daniel S. Ramsey -S
2018.09.28 12:03:45 -04'00'

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)*
K180973

Device Name
Libertas™ Hip Replacement System

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 and 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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K180973

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92.

Applicant
Maxx Orthopedics Inc.
531 Plymouth Road, Suite 526
Plymouth Meeting, PA 19462 USA

Date of Summary: September 26, 2018

Maxx Orthopedics Contact Information:

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Washington, DC 20001
Email: hrhodes@mcra.com
Phone: +1-202-552-5807

Device information:

Proprietary Name:	Libertas™ Hip Replacement System
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 Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350
Product Codes:	JDI, LZO
Device Class:	Class II

Predicate Devices

Component	Predicate Device	Manufacturer	Submission Number
Acetabular Cup System	Latitud Hip System	Meril	K172857
	Corin's Trinity Acetabular System Includes Modular shell, Modular liner (HXLPE), Cobalt-Chromium alloy and Biolox® delta Modular Femoral Head, Bone Screw, Apical Hole Occluder and Screw Hole Occluder	Corin USA	K110087, K103120, K130343, K111481: For Shell, HXLPE liner, Cobalt Chromium alloy and Biolox® delta Modular Femoral Head K093472: For Bone screw, Apical Hole Occluder and Screw Hole Occluder.
	DePuy's Pinnacle acetabular cup system is identified as a reference device	DePuy Orthopaedics Inc.	K000306, K033273
Uncemented femoral stem	DePuy's Corail® HA Coated hip Stem	DePuy Orthopaedics	510(k) Number: K042992
	Latitud Hip System	Meril	K172857
Cemented femoral stem	Stryker's Exeter® Hip Stem (Includes Cemented stem, Cement restrictor and Centralizer)	Stryker®, Howmedica Osteonics, USA	510(k) Number: K110290: Stem K933077: Cement restrictor K974054 : Centralizer
	Latitud Hip System	Meril	K172857

Device Description:
The Libertas™ Hip Replacement System consists of the following components:

- **Acetabular Cup System**
  - Modular Shell
  - Modular Liner HXLPE
  - Cobalt Chromium alloy Modular Femoral Head
  - Biolox® delta Modular Femoral Head

- **Femoral Stem**
  - Uncemented Femoral Stem
  - Cemented Femoral Stem

- **Accessories (Sub components)**
  - Bone Screw
  - Apical Hole Occluder
  - Centralizer
  - Cement Restrictor
  - Screw Hole Occluder

Indications for Use:

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 an evidence of sufficient sound bone to fix and support the components.

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NOTE:

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

Comparison of Technological Characteristics:

The Libertas™ Hip Replacement System is substantially equivalent to the previously cleared predicate devices based on similarities in intended use, device design/technological characteristics, materials, and sterilization method.

Non Clinical Performance Data:

The components of Libertas™ Hip Replacement System were subjected to the following non-clinical performance testing to evaluate device function/mechanical performance.

- Axial Disassembly (Push Out) test (ASTM F 1820-2013)
- Offset pull out (Lever Out) Disassembly (ASTM F 1820-2013)
- Torque Out Disassembly (ASTM F 1820-2013**)**
- Ti coating adhesion (shear) test (ASTM F1044-05; Reapproved 2011)
- HA coating adhesion (shear) test (ASTM F1044-05, Reapproved-2011)
- Impingement test (ASTM F2582-14)
- Fretting Corrosion (ASTM F1875-98; Reapproved 2014)
- Axial pull-off test (ISO 7206-10-2003)
- Proximal fatigue test (ISO 7206-6-2013)
- Distal Fatigue test (ISO 7206-4-2010)
- Range of motion test (ISO 21535-2007)
- Bone Screw Torsion properties (ASTM F543-13e)
- Bone Screw Pull out properties (ASTM F543- 13e)
- Bone Screw Driving torque test (ASTM F543- 13e)
- Bone Screw Self tapping performance (ASTM F543- 13e)
- Burst test, Fatigue test, Post fatigue burst test, Pull-off test for Biolox® delta Modular Femoral head (ISO 7206-10)
- Torque test for Biolox® delta Modular Femoral head (ASTM F1820)
- Material characterization of HXLPE material.
- Engineering rationale for wear test

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, materials, and sterilization method, the Libertas™ Hip Replacement System is considered substantially equivalent to the previously cleared predicate devices.