October 29, 2026

Maxx Orthopedics, Inc.
Donald Guthner
Regulatory Consultant
2460 General Armistead Ave.
Norristown, Pennsylvania 19403

Re: K260975
Trade/Device Name: Libertas Acetabular Liners (Acetabular Liner)
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JDI, LZO, OQI
Dated: September 30, 2026
Received: October 2, 2026

Dear Donald Guthner:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding

When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LIMIN SUN -S

Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260975

Device Name
Libertas Acetabular Liners (Acetabular Liner)

Indications for Use *(Describe)*
Intended 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 evidence of sufficient sound bone to fix and support the components.

Indications for Use:
- 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K260975

510(k) Summary

Prepared on: 2026-10-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Maxx Orthopedics, Inc.
Applicant Address	2460 General Armistead Ave. Norristown PA 19403 United States
Applicant Contact Telephone	646-460-2984
Applicant Contact	Mr. Donald Guthner
Applicant Contact Email	don.guthner@maxxortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Libertas Acetabular Liners (Acetabular Liner)
Common Name	Hip acetabular liner
Classification Name	Hip joint metal/polymer semi-constrained cemented prosthesis
Regulation Number	888.3350
Product Code(s)	JDI, LZO, OQI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
180973	Libertas Hip Replacement System	JDI
K183365	Libertas Acetabular Hooded Liner	LZO
K252067	Velora Acetabular System	LPH
K251833	EMPOWR Acetabular Liner Extension	LPH
K192989	Libertas E-XLPE Modular Liner	OQI

Device Description Summary

21 CFR 807.92(a)(4)

The Acetabular Liner implants consist of a range E-CIMA (Ultra-High Molecular Weight Polyethylene blended with Vitamin E) liners.

The Acetabular Liner implants consist of a range of Modular Liners designed for use with an Acetabular Shells. These components are fabricated from GUR 1020-E UHMWPE CONTAINING 0.1% VITAMIN E (E-CIMA 120kGy). Maxx's E-CIMA liner is a cold irradiated, mechanically annealed, Vitamin E (α-Tocopherol) at a concentration of 0.1% by weight blended Ultra High Molecular Weight Polyethylene (irradiated at a radiation dose of 120 kGy). The Acetabular Liners are available in different sizes to accept various sizes of Femoral Heads and Acetabular Shells. The spherical inner geometry of the Liners fits closely with the spherical Femoral Head diameters ranging from 22.2 to 40mm.

The Acetabular Liner Implants are available in four different configurations: Neutral, Elevated Wall, Oblique, and Offset. The Neutral Acetabular Liners feature a flat face which sits flush to the face of an Acetabular Shell. The Elevated Wall Acetabular Liners feature a 4mm tall elevated wall around 180 degrees of the implant. The Oblique Acetabular Liners feature a face-changing 10 degree angled wall, which extends across the diameter of the implant. The Offset Acetabular Liners feature a nominal +4mm offset when compared to the

Neutral Acetabular Liners.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Intended 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 evidence of sufficient sound bone to fix and support the components.
Indications for Use:
- Non-inflammatory degenerative joint diseases including osteoarthritis, post traumatic arthritis and avascular necrosis
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- 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use are the same as primary predicate K180973

Technological Comparison

21 CFR 807.92(a)(6)

The Subject device is equivalent to the primary predicate K180973 Devices in design and principle of operation. The material for the subject device is E-CIMA and the primary predicate device is HXLPE. The Subject device is equivalent in chemical composition and material to the reference predicate K192989.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Clinical data: No clinical data was necessary to support the safety and effectiveness of the subject device.

Non-clinical testing/evaluations conducted:
- Impingement testing (ASTM F2582-20)
- Liner disassembly testing (ASTM F1820-22)
- Range of Motion (ROM) rationale
- Wear testing (ISO 14242)

Conclusion: The results of the testing/evaluations conducted demonstrate the subject device is substantially equivalent to the predicate devices.