January 15, 2026

Maxx Orthopedics, Inc.
Donald Guthner
Regulatory Consultant
2460 General Armistead Ave
Suite 100
Norristown, Pennsylvania 19403

Re: K253171
Trade/Device Name: Libertas Taper Short (TS) Uncemented Femoral Stem (Libertas TS 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, MEH, OQI
Dated: December 16, 2025
Received: December 16, 2025

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.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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 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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253171

Please provide the device trade name(s).

Libertas Taper Short Uncemented Femoral Stem (Libertas TS Stem)

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2026-01-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Maxx Orthopedics, Inc.
Applicant Address	2460 General Armistead Ave Suite 100 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 Taper Short (TS) Uncemented Femoral Stem (Libertas TS Stem)
Common Name	Total Hip Replacement
Classification Name	Hip joint femoral semi-constrained meta/polymer cemented or nonporous uncemented prosthesis
Regulation Number	888.3353
Product Code(s)	LZO, MEH, OQI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183684	Libertas® Taper Uncemented Femoral Stem	LZO
K180973	Libertas Uncemented Femoral Stem	JDI

Device Description Summary

21 CFR 807.92(a)(4)

The Libertas® - Taper Short Uncemented Femoral Stem (the subject device) is a line extension of the Libertas Hip System comprising of hip stem components for uncemented use in total hip arthroplasty. The subject device components are forged out of Ti-6Al-4V compliant with ASTM F136 Standard Specification for Wrought Titanium- 6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications. The subject device adds non-collared and collared hip stem components to the product line, for a more proximally filling uncemented stem option compatible with all standard surgical approaches for total hip arthroplasty, including modern muscle-sparing techniques.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Indications for Use are the same

Technological Comparison 21 CFR 807.92(a)(6)

The geometry of the subject device is equivalent to the previously cleared Libertas Taper Uncemented Femoral Stem (K183684) with modifications to the anterior/posterior size of the stem to create a stem with larger proximal cross-section (more proximally filling stem). The lengths, neck angles, horizontal offsets, medial curvature, medial/lateral sizing, titanium plasma spray coating and trunnion taper features are identical to the previously cleared device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

An evaluation of the subject device with regards to mechanical performance was completed. This included finite element analysis to identify worst case sizes for both Distal Fatigue (Stem Body Endurance) and Proximal Fatigue (Neck Endurance). The identified worst case size stems were then evaluated in Distal and Proximal fatigue testing to verify mechanical strength through the intended lifetime of the device per ISO 7206-6 and 7206-4.

Implant range of motion and impingement were evaluated for the Libertas® Hip Replacement System with the subject device stems per ISO 25135. The evaluation concluded the neck geometries of the subject and predicate stems are identical in the impingement region and the stems are used in combination with all the same femoral heads and acetabular liners. Therefore, the subject stem cannot present a new worst-case for impingement with all compatible liner styles.

The subject device stems were evaluated and confirmed that they do not create a new worst-case for Fretting Corrosion Testing pertaining to the Femoral Head and Femoral Stem Taper Interface per ASTM F1875 conducted on the previously cleared Libertas® Uncemented Femoral Stems (K180973).

Based on the results from the mechanical evaluation, the range of motion and impingement testing, the fretting corrosion analysis and the physical fatigue testing, the overall conclusion supports a decision of substantial equivalence with the predicate device.