



August 25, 2025

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

Re: K243634

Trade/Device Name: Maxx Libertas Bipolar Hip Head (Bipolar Hip)
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metal/Polymer Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KQY
Dated: July 25, 2025
Received: July 25, 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

510(k) Number (if known)

K243634

Device Name

Maxx Libertas Bipolar Hip Head (Bipolar Hip)

Indications for Use (Describe)

The Maxx Libertas Bipolar Head is intended for use in combination with a Maxx Libertas Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other devices or treatments for these indications have failed.

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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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	Maxx Libertas Bipolar Hip Head (Bipolar Hip)
Common Name	Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented
Classification Name	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulation Number	888.3390
Product Code(s)	KWY

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K100761	BioPro Bipolar Head	KWY

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Maxx Libertas Bipolar Head consists of three factory-assembled parts: a cobalt chromium outer shell, a UHMWPE liner, and a UHMWPE retention ring. The outer shell has a highly polished spherical outer surface for articulating with the acetabular joint socket. The liner has an hemispherical inner surface for articulating with the spherical head component of the Libertas femoral stem (28 mm). The retention ring provides a locking function to resist dislocation of the femoral head from the bipolar head.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Maxx Libertas Bipolar Head is intended for use in combination with a Maxx Libertas Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other devices or treatments for these indications have failed.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Indications for Use are the same

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Subject device is identical to the Predicate Device in design, material, chemical composition, principle of operation.

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

Mechanical testing was performed - Range of Motion, Static push-out test and Static Lever-out test.
Engineering analysis for impingement scenarios was performed.

The device performed identical to the predicate device which supports substantial equivalence.