October 31, 2025

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

Re: K252777
Trade/Device Name: Freedom Metaphyseal Cone Implants (Metaphyseal Cones)
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: August 28, 2025
Received: September 2, 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,

Lixin Liu -S

Lixin Liu, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252777

Device Name
Freedom Metaphyseal Cone Implants (Metaphyseal Cones)

Indications for Use *(Describe)*
The Freedom® Total Knee System is indicated for the following:
• Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
• Correction of functional deformities.
• Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy.
• Moderate valgus, varus, or flexion trauma.
• Knee fractures untreatable by other methods.
• Revision surgery where sufficient bone stock and soft tissue integrity are present (For PCK Components, and Primary PCK Components, and Metaphyseal Cones only).

The Freedom Porous Tibial Base Plate, and Cementless Femoral Components, and Metaphyseal Cones are indicated for Cemented or Uncemented use. All other components are indicated for cemented use only.

The Freedom Metaphyseal Cones are additionally indicated for use in addressing tibial bone voids and/or metaphyseal reconstruction.

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) #: K252777

510(k) Summary

Prepared on: 2025-10-29

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	Freedom Metaphyseal Cone Implants (Metaphyseal Cones)
Common Name	Total Knee Joint Replacement
Classification Name	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.
Regulation Number	888.3565
Product Code(s)	MBH, JWH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143393	Triathlon Tritanium Cone Augments	MBH
K241597	Freedom® Total Knee System - Porous Tibial Base Plate	MBH

Device Description Summary

21 CFR 807.92(a)(4)

The subject device, Freedom Knee Metaphyseal Cone implants, is a component addition to the cleared Freedom Total Knee System for addressing tibial bone voids and/or metaphyseal reconstruction. The Freedom Knee Metaphyseal Cone implants are designed with an elliptical shape, scaling larger in the Medial-Lateral (ML) direction than the Anterior-Posterior (AP) direction. The sizes are driven by the ML size, ranging from 25mm to 60mm wide in the ML direction and 29mm to 36mm AP in the AP direction. The cones are all 30mm long and feature a stepped design to further enhance the stability in the proximal-distal direction.

The Freedom Knee Metaphyseal Cone implants feature a large internal diameter to accept the largest possible Freedom Knee Stemmed Tibial Baseplate and Stem Extension possible. The internal diameters grow larger with each implant size, and all feature cement pockets to enhance the stability of the eventual TKA construct. The cone implants also feature 12mm wide relief slots to accept the fins/keel of the Freedom Knee Tibial Baseplate.

The AP and ML sides of the cone implants (which contact the metaphyseal bone) feature a 1mm thick proprietary scaffold structure. This structure, only possible via the additive manufacturing process, is designed to mimic the size and porosity of cancellous bone. The implant is comprised of Ti6Al4V ELI metal certified to ASTM F3001 and is manufactured with significant surface roughness to further add to the hydrophilic nature of the implant.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Freedom® Total Knee System is indicated for the following:
• Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
• Correction of functional deformities.
• Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy.
• Moderate valgus, varus, or flexion trauma.
• Knee fractures untreatable by other methods.
• Revision surgery where sufficient bone stock and soft tissue integrity are present (For PCK Components, and Primary PCK Components, and Metaphyseal Cones only).

The Freedom Porous Tibial Base Plate, and Cementless Femoral Components, and Metaphyseal Cones are indicated for Cemented or Uncemented use. All other components are indicated for cemented use only.

The Freedom Metaphyseal Cones are additionally indicated for use in addressing tibial bone voids and/or metaphyseal reconstruction.

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

The subject device serves very similar indications for use as the Triathlon Tritanium Cone Augments, though the subject device is not indicated for femoral use and the Freedom Knee System is not indicated for fractures or severe degeneration/trauma.

Technological Comparison 21 CFR 807.92(a)(6)

Manufacturing comparison to the primary predicate device, Triathlon Tritanium Cone Augments, was not completed as the manufacturing processes are assumed to be different. Instead, the subject device was compared to the secondary predicate Freedom® Total Knee System - Porous Tibial Base Plate.

The subject device is manufactured by the same vendor who manufactures the predicate Freedom® Total Knee System - Porous Tibial Base Plate. There is only one key difference between the two systems, the predicate system requires additional CNC machining operations (and additional contact materials) not needed for the subject device. All manufacturing processes and contact materials experienced by the subject device are identical to those completed on the predicate device; the subject device does not introduce any new or different contact materials. Thus, while the predicate device requires additional manufacturing operations and contact materials, the subject device is considered to be substantially equivalent with regards to the manufacturing process.

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

A cadaveric simulation was completed to validate the User Needs and Functional Requirements of the Freedom Metaphyseal Cones, including the implants and instrumentation.

An evaluation of the subject device with regards to mechanical performance was completed. This included mechanical testing of the scaffold structure, comparison to previously completed ASTM F1800 dynamic fatigue testing, and a comparative cross-section analysis of the solid body portion of the subject device in comparison to the primary predicate device.

An evaluation of the subject device with regards to biocompatibility was completed. Since the subject device follows the same manufacturing steps as the predicate Freedom® Total Knee System - Porous Tibial Base Plate (not including machine operations), does not introduce any new contact materials, is comprised of the same base material, and features a smaller volume of lattice structure with a more favorable geometry for cleaning material access, the subject device is considered to fall within the scope of previously completed cleaning and biocompatibility assessments.

An evaluation of the subject device with regards to sterilization and sterile packaging was completed. Since the packaging component materials and sealing methods are identical and the subject device is not larger, heavier, or containing any other risk factors pertaining to sterile packaging (sharp edges, etc.), the subject device falls within the scope of previously completed sterilization and sterile packaging validations. In addition, since the base material (Ti6Al4V ELI) is known to not degrade over time, the subject device similarly falls within the scope of previously completed shelf life validations.

The subject device was thoroughly vetted for performance and safety. A mechanical evaluation provided to support substantial equivalence between the subject and predicate devices. The subject device was found to fall within the scope of critical biocompatibility testing completed on the secondary predicate device Freedom® Total Knee System - Porous Tibial Base Plate. Similarly, the subject device falls within the scope of previously completed sterilization, sterile packaging, and shelf life evaluations. Finally, the subject device and corresponding instrumentation were found to satisfy the user needs of qualified surgeon users via cadaveric simulation. In summary, the subject device is found to be verified and validated as safe and effective as the predicate device.