August 4, 2026

Maxx Orthopedics, Inc.
Asawari Hare
Regulatory Associate
2460 General Armistead Ave. #100
Norristown, Pennsylvania 19403

Re: K261609
Trade/Device Name: Freedom Partial Knee System
Regulation Number: 21 CFR 888.3520
Regulation Name: Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HSX
Dated: June 3, 2026
Received: June 4, 2026

Dear Asawari Hare:

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 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 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, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261609

Device Name
Freedom Partial Knee System

Indications for Use *(Describe)*
The Maxx Orthopedics Freedom® Partial Knee comprising the femoral component, tibial component and tibial insert is designed for a single compartment replacement of the natural knee joint. The Freedom Partial Knee is indicated for cemented use in partial/unicompartmental knee arthroplasty procedures. Partial replacement of the articulating surfaces of the knee is indicated only when only one compartment of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

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) #: K261609

510(k) Summary

Prepared on: 2026-08-03

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Maxx Orthopedics, Inc.
Applicant Address	2460 General Armistead Ave #100 Norristown PA 19403 United States
Applicant Contact Telephone	6177087388
Applicant Contact	Ms. Asawari Hare
Applicant Contact Email	asawari.hare@maxxortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Freedom Partial Knee System
Common Name	Unicompartmental Knee Prosthesis
Classification Name	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis
Regulation Number	888.3520
Product Code(s)	HSX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K212870	Freedom Partial Knee	HSX

Device Description Summary

21 CFR 807.92(a)(4)

General Description

• The Freedom® Partial Knee System is a modular, cemented, unconstrained partial knee prosthesis intended to replace a single compartment of the deficient and damaged tibiofemoral joint surfaces using metal femoral and tibial components, and provide a low-friction articulation with a polyethylene bearing. The system consists of a Cobalt-Chromium-Molybdenum femoral component, an Ultra High Molecular Weight Polyethylene (UHMWPE) tibial insert, and a Titanium alloy tibial baseplate.

Change Introduced

• This submission introduces one additional Partial Tibial Insert thickness (8mm), expanding the existing Partial Tibial Insert range from 9-11mm to 8-11mm. The subject 8mm Partial Tibial Insert has been developed as a line extension of the cleared Freedom® Partial Knee System (K212870) with the intention to provide a more bone conserving implant, expanding upon the already cleared Freedom® Partial Knee.

• The material, articulating surface geometry, and fixation method are equivalent to the cleared predicate device, Freedom® Partial Tibial Insert (K212870). There are no changes to articulation surfaces or condylar geometry.

Principle of Operation

• The device functions in the same manner as the predicate, resurfacing the joint surfaces to restore mobility and alleviate pain associated with degenerative joint disease, and is intended for the same patient population and surgical technique.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Maxx Orthopedics Freedom® Partial Knee comprising the femoral component, tibial component and tibial insert is designed for a

single compartment replacement of the natural knee joint. The Freedom Partial Knee is indicated for cemented use in partial/ unicompartmental knee arthroplasty procedures. Partial replacement of the articulating surfaces of the knee is indicated only when only one compartment of the joint is affected due to the compartmental primary degenerative or post-traumatic degenerative disease, previous tibial condyle or plateau fractures, deformity or revision of previous arthroplasty.

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

Indications for use are the same.

Technological Comparison 21 CFR 807.92(a)(6)

Predicate Device
• Predicate: Freedom Partial Knee (K212870)
• Rationale: The subject device is substantially equivalent to the predicate in intended use, material, articulating surface geometry, and method of fixation. The only modification is the addition of one tibial insert thickness, 8mm.

Discussion
• The subject 8mm Partial Tibial Insert is intended for use with the currently available, FDA Cleared, Freedom® Partial Knee System as part of partial knee replacement surgery. Partial knee replacement surgery is a procedure where worn, diseased, or damaged surfaces of one compartment of the knee joint are removed and replaced with artificial surfaces. The subject implant will be a prescription product consisting of single use only, implantable device for implanting into patients in an operating theatre by a qualified surgeon.
• The device is to be packaged and terminally sterilized by ethylene oxide, identical to the predicate device. The packaging is to keep devices sterilized for 10 years. The packaging will be able to be opened easily in an operating theatre without instruments and in a manner that allows the implant to remain sterile.
• To expand the existing Partial Tibial Insert portfolio, an 8mm thickness is being added for each size offering. The Anterior-Posterior (AP) and Medial-Lateral (ML) profiles are identical, and the overall size ranges are also identical.
• The expansion of available Partial Tibial Insert thicknesses does not alter clinical functionality, mechanical performance, or patient exposure to new materials. Therefore, the differences do not raise different questions of safety or effectiveness.

Design and Specifications
• The subject device shares equivalent articulating surface geometry, material, tolerances, and manufacturing processes with the predicate device. The only modification is the introduction of one additional thickness (8mm), expanding the range from 9-11mm to 8-11mm with the intention to provide surgeons with additional intraoperative flexibility in restoring joint line and soft-tissue balance.
• The articulating surface, contact geometry, and fixation method are unchanged. The subject 8mm Partial Tibial Insert are fabricated from equivalent Ultra High Molecular Weight Polyethylene (UHMWPE) using equivalent machining, cleaning, packaging, and ethylene oxide sterilization processes as the predicate device.

Sterilization and Biocompatibility
• Sterilization, packaging materials, and biocompatibility characteristics are equivalent to those previously cleared for the predicate device.

Accordingly, the added Partial Tibial Insert thickness is fully compatible with existing system components and meet the applicable performance expectations established for the cleared predicate.

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

A wear simulation test was performed at the laboratories of the University of Nebraska Medical Center on the Freedom Partial Knee Replacement design utilizing the new 8mm tibial insert. The standard force-control wear testing method (ISO 14243-1 & 2) was used on a four-station Instron-Stanmore Knee Simulator set up to run as right knees. The test was run for 5 million cycles which loosely approximated to a patient walking for 5 years.

A force-controlled simulation and wear test was conducted to 5 million cycles on the Freedom Partial Knee Replacement components. Medial and lateral systems were paired together to facilitate testing similar to a full Total Knee Replacement. Compared to two other contemporary unicondylar knee replacement designs tested identically at the same laboratory, the wear rates of the Freedom Partial Knee Replacement design utilizing the 8mm tibial insert were lower than the wear rates of the other two systems.

Therefore, similarities in technological characteristics and results from non-clinical performance testing indicate that the Freedom Partial Knee System is substantially equivalent to the predicate device.