March 13, 2025

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

Re: K250382
Trade/Device Name: Freedom Total Knee System (All-poly Tibial Plate)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: February 4, 2025
Received: February 11, 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, 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.

Submission Number *(if known)*

K250382

Device Name

Freedom Total Knee System (All-poly Tibial Plate)

Indications for Use *(Describe)*

• 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 only).

The Freedom Total Knee System, Freedom Stemmed Tibial Components and Freedom PCK Components are indicated for cemented fixation

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) #: K250382

510(k) Summary

Prepared on: 2025-03-13

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 Total Knee System (All-poly Tibial Plate)
Common Name	Tibial Baseplate
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	21 CFR 888.3560
Product Code(s)	JWH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K082019	Freedom All-poly Tibial Baseplate	JWH
K090411	Freedom Metal Tibial baseplate	JWH
K182574	Freedom UC Tibial Liner	JWH
K243277	Freedom MC Tibial Liner	JWH
K131481	FREEDOM PCK COMPONENTS	JWH

Device Description Summary

21 CFR 807.92(a)(4)

The Freedom Total Knee System All-Poly Tibial Plate implants have been developed with the desire to expand upon the already clinically successful Freedom® Total Knee System, melding together the best design features of various sub-systems into one. The implants will retain the key benefits of the All-Poly Tibial implant system while leveraging some of the newer technology introduced in the modular, metal-backed systems (K090411, K182574, K243277). Using the All-Poly design, the articular surface, tibial baseplate, and stem are manufactured from a single component. This eliminates the risks/issues stemming from modularity, reduces the overall weight and subsidence risk, adds full radiolucency to the tibial implants, and comes at a reduced cost. Like the original All-Poly Implants, these new versions will be manufactured from GUR 1020 (Type 1) UHMWPE per ASTM F648.

To enhance the existing All-Poly Implant designs, the stem of these implants is being upgraded to the larger, finned stem/keel design from the modular Freedom® Total Knee System (K090411). This will provide the new All-Poly Tibial implants with enhanced stability post-operatively and allow surgeons to use the same instruments/surgical technique as the modular, metal-backed system. This will improve the harmony between the various Freedom® systems and ensure all products produce the same strong clinical results.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

• 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 only).

The Freedom Total Knee System, Freedom Stemmed Tibial Components and Freedom PCK Components are indicated for cemented fixation

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

The Indications for use for the All-poly Tibial Plate implants are the same as the K082019 predicate with additional indications related to use of PCK revision components (K131481) from the Freedom Total Knee System.

Technological Comparison 21 CFR 807.92(a)(6)

The new All-Poly Tibial implants are designed to work exactly the same as the existing All-Poly and modular, metal-backed Freedom® system components. The Anterior-Posterior (AP) and Medial-Lateral (ML) profiles are identical, and the overall size ranges are also the same. The All-Poly Tibial implants will come in multiple articular surface types. The Posterior-Stabilized articular surface is identical to those cleared in K082019, the Ultracongruent articular surface is identical to those cleared in K182574, and the Medial Congruent articular surface is identical to those cleared in K243277. This will provide the surgeons with the full portfolio of Freedom® bearing surfaces without needing to use the modular, metal-backed versions.

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

A series of comparative analyses were completed to evaluate the new Freedom Total Knee System All-Poly Tibial Implants in the scope of the verification and validation testing completed for the predicate devices.
The engineering drawing specifications of the new All-Poly Tibial implants were compared to the equivalent engineering drawing specifications of the predicate systems. This review demonstrated that the new All-Poly Tibial implants were equivalent to their predicate devices in both implant geometry and material. Next, analyses of the mechanical properties and biological properties of the All-Poly Tibial Baseplate were completed to determine if these new Ultracongruent and Medial Congruent tibial components would fall within the scope of previously completed verification testing. The new All-Poly Tibial implants do not create a new worst- case for mechanical, cleaning, sterilization, or sterile packaging, and therefore fall within the scope of the equivalent verification testing completed for the predicate devices. Comparisons of the device geometry and articulating surface demonstrate that the device performance properties, including Range of Motion and Constraint, Component Interlock Strength / Disassembly, Contact Area and Stress, and Wear Resistance are equivalent to the previously cleared predicate devices. Finally, a similar comparative analysis was completed to determine if the new All-Poly tibial implants fall within the scope of previously completed validation testing and confirmed that the implantation process, surgical technique, and implant stability/performance will be identical to the existing predicate device counterparts and that additional clinical simulation or other validation activities are not necessary.
Since the new All-Poly Tibial Implants fall within the scope of all relevant verification and validation testing, the evaluation is acceptable to demonstrate the subject Ultracongruent and Medial Congruent tibial components do not raise different questions of safety and effectiveness and are substantially equivalent to the predicate devices.