June 26, 2025

Maxx Orthopedics Inc.
% Bittu Jha
Manager - Regulatory Affairs
Meril Healthcare Pvt. Ltd.
H1 - H3, Meril Park, Survey No 135/2/B & 174/2
Muktanand Marg, Chala
Vapi, Gujarat 396191
India

Re: K251717
Trade/Device Name: Freedom® Total Knee System - Titanium Tibial Base 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: June 3, 2025
Received: June 4, 2025

Dear Bittu Jha:

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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2025.06.26 17:31:49 -04'00'

For 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

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.	K251717

Please provide the device trade name(s).

Freedom® Total Knee System - Titanium Tibial Base Plate

Please provide your Indications for Use below.

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 only).
The Freedom® Total Knee System - Titanium Tibial Base Plate is intended for cemented and single 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)

I. *SUBMITTER*

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Applicant Information

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Date Prepared: June 02, 2025

II. *SUBJECT DEVICE*

Trade / Proprietary Name	Freedom® Total Knee System – Titanium Tibial Base Plate
Common Name	Total Knee Replacement
Classification	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class	II
Product Code	JWH
Regulation Number	21CFR 888.3560
Review Panel	Orthopedic

III. *PREDICATE DEVICE*

Device Category	Product Code	Trade Name	Manufacturer	510(k)
Primary Predicate	JWH	Freedom® Metal Backed Tibial Component	Maxx Orthopedics Inc.	K090411
Additional Predicate	MBH, JWH	Freedom® Total Knee System – Porous Tibial Base Plate		K241597

IV. *DEVICE DESCRIPTION*

The Freedom® Total Knee System is comprised of a femoral component, all-poly tibial component, patellar component, tibial base plate and tibial articular surface. The Freedom® Total Knee System's Femoral Component is offered as different versions such as stemmed PCK design, primary PCK, cruciate retaining, posterior stabilizing. The Freedom® Total Knee System's

Tibial Base Plate is offered with stemmed design and without stemmed design. The Freedom® Total Knee System was originally cleared under the 510(k) number K082019. Later on, several modifications were made and were cleared under 510(k)s K091280, K192148, K090411, K182574, K131481, K111785 and K200912 respectively.

The primary purpose of this special 510(k) Device Modification to the Freedom® Metal Backed Tibial Component (K090411) is to notify the FDA of the change in materials used to manufacture the tibial base plate from CoCrMo to Wrought Titanium-6Aluminium-4Vanadium ELI Alloy (Ti6Al4V ELI, ASTM F136-13) as an alternative material option for the tibial base plate.

The Titanium Tibial Base Plate is fabricated from Titanium alloy Ti-6Al-4V ELI, compliant with ASTM F136 and is intended for cemented application to replace the articulating surface of the proximal tibia in a measured resection technique.

The Titanium Tibial Base Plates are available in 8 different sizes (1 to 8) based on Anterior/Posterior (A/P) and Medial/Lateral (M/L) dimensions.

V. ***INDICATIONS FOR USE***

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 only).

The Freedom® Total Knee System – Titanium Tibial Base Plate is intended for cemented and single use only.

VI. *PERFORMANCE TESTING*

The Freedom® Total Knee System – Titanium Tibial Base Plate is comprised Tibial Base Plate manufactured from Titanium alloy Ti-6Al-4V ELI, compliant with ASTM F136 – *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.* The design, geometry, surface features, locking features and dimensional attributes of the Titanium Tibial Base Plate are identical to those of the previously cleared Freedom® Metal Backed Tibial Base Plate (K090411). The only change is in material of construction. Hence, to evaluate the device function and performance for its intended use, the Freedom® Titanium Tibial Base Plate was subjected to the following mechanical tests:

- Tibial Tray Fatigue Testing per ASTM F1800

Range of Motion & Modular disassembly testing was leveraged from the reference device (K090411) as the subject device uses an identical tibial insert locking mechanism.

VII. *BIOCOMPATIBILITY*

Biocompatibility testing is not required for the subject Titanium Tibial Base Plate device, because the material, Ti-6Al-4V ELI Titanium Alloy is compliant with ASTM F136, is a well-established material with a long history of safe use in orthopedic implants.

This material has been used extensively for many years without any major biocompatibility related safety concerns.

Additionally, the material has been used in multiple components of Maxx Orthopedics' previously cleared Freedom® Total Knee System, such as:

- Posterior & Distal Femoral Augments – Freedom® PCK Femoral Components (K131481)
- Stem Extension, Offset Junction & Tibial Augments – Freedom® Stemmed Tibial Components (K111785)

It also complies with the biocompatibility requirements outlined in "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA"

Furthermore, Ti-6Al-4V ELI Titanium Alloy (ASTM F136) has also been used in similar tibial base plate components from other legally marketed devices, intended for same anatomical location and patient contact type, as demonstrated in K220737.

A risk-based assessment, following the principles outlined in FDA's 2023 Biocompatibility guidance (Use of ISO 10993-1), confirms that the material change does not introduce new types of patient contact, contact duration, or clinical use conditions that would require additional biocompatibility testing.

VIII. *TECHNOLOGICAL CHARACTERISTICS*

There are no significant technological differences between the subject and predicate device. The subject device uses a similar design and dimensions, geometry and sizing, and achieves its intended use in an identical manner as the primary predicate and both devices are manufactured using similar subtractive manufacturing techniques. Minor differences in subject device are that it uses different materials of constructions and sterilization method that are addressed via performance testing and similarity to the secondary predicate devices (K241597). Hence based on the results of performance testing and similarity to predicate devices, it is concluded that the device modification does not affect or raise new questions on the device's safety and effectiveness.

IX. *CONCLUSION*

Based on the indications for use and fundamental scientific technology supported by performance and biocompatible testing, it is concluded that the subject device is substantially equivalent to the legally marketed predicate devices.