October 22, 2025

Maxx Orthopedics Inc.
% Bittu Jha
Senior 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: K253144
Trade/Device Name: Freedom® Total Knee System - Titan PCK Components
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: September 23, 2025
Received: September 25, 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,

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)*
K253144

Device Name
Freedom® Total Knee System – Titan PCK Components

Indications for Use *(Describe)*
The Freedom® Total Knee System is indicated for patients with severe knee pain and the disability due to:
• 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 – Titan PCK Components are intended for cemented and single use only.

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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I. ***SUBMITTER***

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Date Prepared: October 09, 2025

II. *SUBJECT DEVICE*

Trade / Proprietary Name	Freedom® Total Knee System – Titan PCK Components
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 880.3560
Review Panel	Orthopedic

III. *PREDICATE DEVICES*

Device Category	Product Code	Trade Name	Manufacturer	510(k)
Primary Predicate	JWH	Freedom® PCK Femoral Components	Maxx Orthopedics Inc.	K131481
Secondary Predicate	JWH	Freedom® Stemmed Tibial Components		K111785

IV. *REFERENCE DEVICES*

Device Category	Product Code	Trade Name	Manufacturer	510(k)
Reference Device	JWH	Freedom® TiNbN Coated Knee	Maxx Orthopedics Inc.	K200912
Reference Device	JWH	Freedom® Total Knee System		K240863

V. ***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, K200912, and K240863 respectively.

This submission seeks the clearance of Titanium Niobium Nitride (TiNbN) coated version of previously cleared Femoral Augment (non-coated version cleared in K131481), Tibial Augments, Stem Extension & Offset Junction (non-coated versions cleared in K111785). The coated versions are now branded as Freedom® Total Knee System – Titan PCK Components.

Below is the description of the coated components.

Freedom® Titan Femoral Augments

The Freedom® Titan Femoral Augments are fabricated from Titanium-6Aluminum-4Vanadium (Ti-6A1-4V), complaint with ASTM F136, and are coated with Titanium Niobium Nitride (TiNbN). These augments are intended to be screwed to the internal distal and posterior surfaces of the previously cleared PCK Stemmed Femoral Component (K131481) and Titan PCK Stemmed Femoral Component (K240863) when required in cases of significant bone loss. The augments are designed to be stackable and for use on either the medial or lateral side.

Augment Screws, fabricated from Titanium-6Aluminum-4Vanadium (Ti-6A1-4V), complaint with ASTM F136, and are coated with Titanium Niobium Nitride (TiNbN), are available as an accessory to the system to fix the augments to the Stemmed Femoral Component and other augments.

The Freedom® Titan Femoral Augments is available in distal and posterior design configuration. Each configuration is further available in 6 different sizes.

Freedom® Titan Tibial Augments

The Freedom® Titan Tibial Augments are fabricated from Titanium-Aluminum-Vanadium (Ti-6A1-4V), complaint with ASTM F136, and are coated with Titanium Niobium Nitride (TiNbN). These augments are intended to be screwed to the distal surface of the previously cleared Stemmed Tibial Base Plate (K111785) & Titan Stemmed Tibial Base Plate (K240863) when required in cases of significant bone loss. The augments are designed to be stackable, using a system of pins, bosses and screws, and reversible for use on either the medial or lateral side.

Augment Screws, fabricated from Titanium-6Aluminum-4Vanadium (Ti-6A1-4V), complaint with ASTM F136, and are coated with Titanium Niobium Nitride (TiNbN), are available as an accessory to the system to fix the augments to the Stemmed Tibial Base Plate and other augments.

Freedom® Titan Offset Junction

The Freedom® Titan Offset Junctions are fabricated from Titanium-Aluminum-Vanadium (Ti-6A1-4V), complaint with ASTM F136, and are coated with Titanium Niobium Nitride (TiNbN). Offset Junctions are intended to be used with the previously cleared Stemmed Tibial Base Plate (K111785) & Titan Stemmed Tibial Base Plate (K240863) to provide an additional 4mm or 6mm offset between the tibial keel and stem. The Offset Junction is attached to the tibial component and stem through taper junctions. A set-screw is supplied with the Offset Junction to provide additional locking during extraction.

Freedom® Titan Stem Extension

The Freedom® Titan Stem Extensions are fabricated from Titanium-Aluminum-Vanadium (Ti-6A1-4V), complaint with ASTM F136, and are coated with Titanium Niobium Nitride (TiNbN). The Titan Stem Extensions are intended for use with the previously cleared Stemmed Tibial Base Plate (K111785) & Titan Stemmed Tibial Base Plate (K240863). The Stem Extensions are

available in a range of diameters and lengths and are fluted distally with a distal slot in the larger lengths and diameters.

VI. *INDICATIONS FOR USE*

The Freedom® Total Knee System is indicated for patients with severe knee pain and the disability due to:

- 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 – Titan PCK Components are intended for cemented and single use only.

VII. *PERFORMANCE TESTING*

The presence of TiNbN coating is the only change in this submission. To evaluate the device function and performance of the coating for its intended use, the coated components as well as representative samples with the TiNbN Coating was subjected to the following coating tests:

- Coating Thickness
- Coating Hardness
- Coating Adhesion Strength

Additionally, the below listed mechanical and functional tests are leveraged from the testing performed on Freedom® PCK Components (K131481) and Freedom® Stemmed Tibial

Components (K111785). The cleared uncoated devices are the part of Freedom® Total Knee System and are identical to the Titan Femoral Augment, Titan Tibial Augment, Titan Stem Extension and Titan Offset Junction except for the TiNbN coating on the surface. However, the TiNbN coating does not have any effect on these mechanical and functional tests. Therefore, the testing performed on the cleared uncoated Freedom® PCK Components and Freedom Stemmed Tibial Components can be leveraged for the subject device.

- Static and Dynamic Properties of the Freedom PCK Tibial Post
- Modular Disassembly Characteristics of the Freedom PCK Tibial Insert
- Determination of the Range of Motion of the Freedom PCK
- Stability Characteristics of the Freedom PCK Components
- Stability Characteristics of the Freedom PCK Components at High Flexion
- Axial Disassembly Properties of the Freedom Modular Stemmed Tibial Component
- Disassembly Properties of the Freedom Modular Tibial Augment
- Modular Augment Damage Analysis of the Freedom Knee Stemmed Tibial Tray Assembly
- Modular Taper Analysis of the Freedom Knee System Stemmed Tibial Tray

VIII. *BIOCOMPATIBILITY*

The biocompatibility tests are leveraged from the testing performed on Freedom® TiNbN Coated Knee (K200912). The cleared K200912 device has the same coating as the subject devices. Therefore, the biocompatibility testing performed on the cleared Freedom® TiNbN Coated Knee can be leveraged for the subject device.

IX. *SUBSTANTIAL EQUIVALENCE DISCUSSION*

There are no significant technological differences between the subject and predicate device. The subject devices Freedom® Total Knee System – Titan PCK are same as the predicate devices in terms of fundamental scientific technology; design and dimensions, geometry and sizing,

device's operating mechanism, base material composition, and intended use and indications for use.

The presence of TiNbN coating is the only change. The coating is equivalent to the previously cleared Freedom® TiNbN Coated Knee (K200912) and Freedom® Total Knee System – Titan Stemmed PCK Femoral Component & Titan Stemmed Tibial Base Plate (K240863). Based on the results from design hazard analysis and performance testing, it is concluded that the device modification does not raise different questions on the device's safety and effectiveness. The subject device is substantially equivalent to the proposed predicate devices.

X. ***CONCLUSION***

Based on the intended use, 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.