July 2, 2024

Maxx Orthopedics Inc.
% Bittu Jha
Assistant Manager - Regulatory Affairs
Meril Healthcare Pvt. Ltd.
H1 - H3, Meril Park, Survey No 135/2/B & 174/2
Muktanand Marg, Chala
Vapi, Gujarat 396171
India

Re: K240863
Trade/Device Name: Freedom® Total Knee System
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: April 24, 2024
Received: April 24, 2024

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.

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)*

K240863

Device Name

Freedom® Total Knee System

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.

The Freedom® Total Knee System is intended for cemented and for 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.

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510(k) SUMMARY

I. *SUBMITTER*

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Alternate Correspondent Information

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Date Prepared: July 02, 2024

II. *SUBJECT DEVICE*

Trade / Proprietary Name	Freedom® Total Knee System
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® Total Knee System	Maxx Orthopedics Inc.	K082019
Additional Predicate	JWH	Freedom® PCK Components		K131481
Additional 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	Opulent TiNbN Coated Knee	Meril Healthcare Pvt. Ltd.	K222816

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 and K200912 respectively.

This submission seeks the clearance of Titanium Niobium Nitride (TiNbN) coated version of previously cleared Stemmed PCK Femoral Component (non-coated version cleared in K131481) and Stemmed Tibial Base Plate (non-coated version cleated in K111785). The coated versions are now branded as Titan PCK Stemmed Femoral Component and Titan Stemmed Tibial Base Plate.

Both these components are manufactured from CoCrMo alloy and are coated completely with Titanium Niobium Nitride (TiNbN).

Below is the description of the coated components:

Titan PCK Stemmed Femoral Component

The Titan PCK Stemmed Femoral Component with progressive constraint (PCK) is fabricated from Cobalt-Chromium-Molybdenum (CoCrMo), completely coated with Titanium Niobium Nitride (TiNbN) and is intended for cemented application to replace the articulating surface of the distal femur in a measured resection technique. The Titan PCK Stemmed Femoral Component is available in left and right configurations. Each configuration is further available in 8 different sizes (A to H) based on Anterior/Posterior (A/P) and Medial/Lateral (M/L) dimensions.

Titan Stemmed Tibial Base Plate

The Titan Stemmed Tibial Base Plate is fabricated from Cobalt-Chromium-Molybdenum (CoCrMo), completely coated with Titanium Niobium Nitride (TiNbN) and is intended for cemented application to replace the articulating surface of the proximal tibia in a measured

resection technique. The Titan Stemmed Tibial Base Plates are available in 8 different sizes (1 to 8) based on Anterior/Posterior (A/P) and Medial/Lateral (M/L) dimensions and are supplied with UHMWPE plugs to close off augment screw holes and distal taper when not used and with a set screw to provide additional locking to the stem or offset junction during extraction.

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.

The Freedom® Total Knee System components are intended for cemented and for single use only.

VII. *PERFORMANCE TESTING*

The presence of TiNbN coating and the sterilization method are the only changes 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 mechanical tests:

- Wear Resistance
- Coating Chemical Composition
- Coating Thickness
- Coating Hardness

- Coating Adhesion Strength
- Roughness

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 PCK Stemmed Femoral Component and the Titan Stemmed Tibial Base Plate, 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. *SUBSTENCIAL EQUIVALENCE DISCUSSION*

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 subject device Freedom® Total Knee System with the coated Titan PCK Stemmed Femoral Component and the coated Titan Stemmed Tibial Base Plate is same as the predicate devices in terms of fundamental scientific technology; device's operating mechanism, base material composition, and intended use and indications for use.

The presence of TiNbN coating and the sterilization method are the only changes. The coating and sterilization are equivalent to the previously cleared Freedom® TiNbN Coated Knee (K200912) and Opulent TiNbN Coated Knee (K222816).

Based on the results from design hazard analysis and performance testing, it is concluded that the device modification does not affect or raise different questions on the device's safety and effectiveness. The subject device with the Titan PCK Stemmed Femoral Component and the Titan Stemmed Tibial Base Plate is substantially equivalent to the proposed predicate devices.

X. *CONCLUSION*

Based on the intended use, indications for use and fundamental scientific technology supported by performance and biocompatibility testing, it is concluded that the Freedom® Total Knee System with the coated Titan PCK Stemmed Femoral Component and the coated Titan Stemmed Tibial Base Plate is substantially equivalent to the proposed predicate devices.