



October 29, 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: K253314

Trade/Device Name: Freedom Infinia™ 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, MBH

Dated: September 29, 2025

Received: September 30, 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

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.

K253314

?

Please provide the device trade name(s).

?

Freedom Infinia™ Total Knee System

Please provide your Indications for Use below.

?

The Freedom Infinia™ 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 Infinia™ Total Knee System components are intended for cemented and single use only. The Freedom Infinia™ Cementless Femoral (CR and PS) Components and Porous Tibial Base Plates are additionally indicated for cementless biological fixation application

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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Date Prepared: September 29, 2025

II. SUBJECT DEVICE

Trade / Proprietary Name	Freedom Infinia™ Total Knee System
Common Name	Total Knee Replacement
Classification	<ul style="list-style-type: none"> • Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis • Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class	II
Product Code	<ul style="list-style-type: none"> • JWH • MBH
Regulation Number	<ul style="list-style-type: none"> • 21CFR 880.3560 • 21CFR 880.3565
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® Total Knee Metal Backed Tibial Components		K090411
Additional Predicate	JWH	Freedom® Stemmed Tibial Components		K111785
Additional Predicate	JWH	Freedom® PCK Components		K131481
Additional Predicate	MBH	Freedom® Cementless Femoral Components		K150680
Additional Predicate	JWH	Freedom® Ultra-Congruent CR Tibial Liner		K182574

Device Category	Product Code	Trade Name	Manufacturer	510(k)
Additional Predicate	JWH	Freedom® Primary PCK		K192148
Additional Predicate	MBH	Freedom® Total Knee System - Porous Tibial Base Plate		K241597
Additional Predicate	JWH	Freedom® Medial Congruent Liner		K243277
Additional Predicate	JWH	Freedom® Total Knee System - Titanium Tibial Base Plate		K251717

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 K090411, K091280, K111785, K131481, K150680, K182574, K192148, K241597, K243277, K251717 respectively.

This submission seeks the clearance of an additional brand, Freedom Infinia™ Total Knee System.

Below is the description of the Freedom Infinia™ Total Knee System’s components.

Freedom Infinia™ Femoral Component

The Freedom Infinia™ Total Knee System's Femoral Component is offered in both cruciate retaining and posterior stabilizing designs. The Femoral components are available in right and left configurations, and eight sizes to accommodate varying anatomy. The Freedom Infinia™

Total Knee System's Femoral Component is fabricated from Cobalt-Chromium-Molybdenum (CoCrMo) alloy complying with ASTM F75 and is intended for cemented application to replace the articulating surface of the distal femur in a measured resection.

Freedom Infinia™ Cementless Femoral Component

The Freedom Infinia™ Total Knee System's Cementless Femoral Component is offered in both cruciate retaining and posterior stabilizing designs. The Cementless Femoral Components are available in right and left configurations, and eight sizes to accommodate varying anatomy. The Freedom Infinia™ Total Knee System's Cementless Femoral Component is fabricated from Cobalt-Chromium-Molybdenum (CoCrMo) alloy complying with ASTM F75 and porous coated CoCr beads and is intended for cementless biological fixation application to replace the articulating surface of the distal femur in a measured resection.

Freedom Infinia™ Stemmed Femoral Component

The Freedom Infinia™ Total Knee System's Stemmed Femoral Component with progressive constraint (PCK) is fabricated from Cobalt-Chromium-Molybdenum (CoCrMo) alloy complying with ASTM F75, intended for cemented application to replace the articulating surface of the distal femur in a measured resection technique. It 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. Thus total of 16 models are available for the Stemmed Femoral Component.

Freedom Infinia™ Femoral Augments

The Freedom Infinia™ Total Knee System's Femoral Augments are fabricated from Titanium-6Aluminum-4Vanadium (Ti-6Al-4V), complaint with ASTM F136. These augments are intended to be screwed to the internal distal and posterior surfaces of Freedom Infinia™ PCK Stemmed Femoral Component 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-6Al-4V), compliant with ASTM F136, are available as an accessory to the system to fix the augments to the Freedom Infinia™ Stemmed Femoral Component and other augments.

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

Freedom Infinia™ Primary PCK Femoral Component

Freedom Infinia™ Total Knee System's Primary PCK Femoral Component is designed to be used with the Freedom Infinia™ Stemmed Tibial Components. It is fabricated from Cobalt- Chromium-Molybdenum (CoCrMo) alloy complying with ASTM F75 and is intended for cemented application.

Freedom Infinia™ Tibial Base Plate

The Freedom Infinia™ Total Knee System's Tibial Base Plate is fabricated from Cobalt- Chromium-Molybdenum (CoCrMo) alloy complying with ASTM F75 and is intended for cemented application to replace the articulating surface of the proximal tibia in a measured resection technique. The Tibial Base Plates are available in 8 different sizes (1 to 8) based on Anterior/Posterior (A/P) and Medial/Lateral (M/L) dimensions.

Freedom Infinia™ Titanium Tibial Base Plate

The Freedom Infinia™ Total Knee System's Titanium Tibial Base Plate is fabricated from Wrought Titanium alloy Ti-6Al-4V ELI, compliant with ASTM F136-13 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.

Freedom Infinia™ Porous Tibial Base Plate

The Freedom Infinia™ Total Knee System's Porous Tibial Base Plate is intended for use with existing, compatible Femoral Components and Tibial Liner Components. Freedom Infinia™ Porous Tibial Base Plates are additively manufactured from Ti-6Al-4V ELI Grade 23 and include a

porous lattice structure on the distal face. Freedom Infinia™ Porous Tibial Base Plates are available in eight asymmetric design offerings (Sizes 1 – 8, Left / Right configurations), based on anterior / posterior (A/P) and medial / lateral (M/L) dimensions.

Freedom Infinia™ Stemmed Tibial Base Plate

The Freedom Infinia™ Total Knee System's Stemmed Tibial Base Plate is fabricated from Cobalt-Chromium-Molybdenum (CoCrMo) alloy complying with ASTM F75 and is intended for cemented application to replace the articulating surface of the proximal tibia in a measured resection technique. The 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.

Freedom Infinia™ Tibial Augments

The Freedom Infinia™ Total Knee System's Tibial Augments are fabricated from Titanium-Aluminum-Vanadium (Ti-6Al-4V), compliant with ASTM F136. These augments are intended to be screwed to the distal surface Freedom Infinia™ Stemmed Tibial Base Plate 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-6Al-4V), compliant with ASTM F136, are available as an accessory to the system to fix the augments to the Stemmed Tibial Base Plate and other augments.

Freedom Infinia™ Stem Extension

The Freedom Infinia™ Total Knee System's Stem Extensions are fabricated from Titanium-Aluminum-Vanadium (Ti-6Al-4V), compliant with ASTM F136. The Freedom Infinia™ Stem Extensions are intended for use with Freedom Infinia™ Stemmed Tibial Base Plate. The Freedom Infinia™ 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.

Freedom Infinia™ Offset Junction

The Freedom Infinia™ Total Knee System's Offset Junctions are fabricated from Titanium-Aluminum-Vanadium (Ti-6Al-4V), compliant with ASTM F136, are intended to be used with the Freedom Infinia™ Stemmed Tibial Base Plate to provide an additional 4mm or 6mm offset between the tibial keel and stem. Freedom Infinia™ 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 Infinia™ Tibial Liner

The Freedom Infinia™ Total Knee System's Tibial Liner is available in two designs i.e. posterior stabilizing (PS) and cruciate retaining (CR). Based on the Tibial Liner compatibility with Femoral Component configurations, each PS and CR designs are available various sizes with different anterior/posterior (A/P) and medial/lateral (L/P) dimensions, and each size is further bifurcated as on thickness. Tibial liner is fabricated from Ultra High Molecular Weight Polyethylene (UHMWPE) complying with ASTM F648 and is intended for cemented application along Tibial Base Plate to replace the articulating surface of the proximal tibia in a measured resection. Both the CR and PS Tibial Liners have identical locking mechanisms to mate with the Tibial Base Plate.

Freedom Infinia™ Medial Congruent Liner

The Freedom Infinia™ Total Knee System's Medial Congruent Liners have been developed with the desire to achieve a higher level of constraint than typically achieved in a traditional CR knee design while also providing the femoral component with a medial-pivoting motion throughout a range of motion. They possess an anterior and buildup and a higher sagittal conformity of the medial compartment that interact with the femoral component, to provide additional constraint. Designed to be used with the CR Femoral Component. Eliminates the need to remove bone for a PS box. Designed to allow high flexion. Includes a deep anterior patellar cut-out to allow for tendon clearance. Facilitates intraoperative flexibility, given compatibility with existing femoral and tibial baseplate options.

Freedom Infinia™ Ultra-Congruent CR Tibial Liner

The Freedom Infinia™ Total Knee System's Ultra-Congruent CR Tibial Liner consists of an ultra-high molecular weight polyethylene (UHMWPE) liner complies with ASTM F648 that is designed to be used with the Freedom Infinia™ Total Knee Cruciate Retaining (CR) Femoral Components in the Freedom Infinia™ Total Knee System.

Freedom Infinia™ PCK Tibial Liner

The Freedom Infinia™ Total Knee System's PCK Tibial Liner is fabricated from Ultra High Molecular Weight Polyethylene (UHMWPE) complies with ASTM F648. Based on the Tibial liner compatibility with PCK femoral component configurations, each PCK tibial liner design is available different sizes with different anterior/posterior (A/P) and medial/lateral (L/P) dimensions, and each size is further bifurcated on thickness variants.

The PCK Tibial Liners consist of the same articulating surface of existing Tibial liner components and have a same locking mechanism on the peripheral edge of the distal surface to lock into the Tibial / Stemmed Tibial Base Plate. The PCK tibial liner supplied with a liner securing pin manufactured from Ti-6Al-4V ELI to provide additional locking with stemmed tibial base plate.

Freedom Infinia™ All Poly Tibial Component

The Freedom Infinia™ Total Knee System's All Poly Tibial Component is fabricated from ultra high molecular weight polyethylene (UHMWPE) complying with ASTM F648 and is intended for cemented application to replace the articulating surface of the proximal tibia in a measured resection. Both the Total Knee System CR and PS Tibial Inserts have identical locking mechanisms to mate with the Tibial Base Plate.

Freedom Infinia™ All Poly Patella

The Freedom Infinia™ Total Knee System's All Poly Patella is available in symmetrical single radius design. Based on different diameter and thickness different models are available. All Poly Patella is fabricated from Ultra High Molecular Weight Polyethylene (UHMWPE) complying with ASTM F648.

The symmetric design features a central cement recess, and three pegs on the bone interface surface. The symmetric patellar component is intended for cemented application via an onset resurfacing surgical technique.

V. INDICATIONS FOR USE

The Freedom Infinia™ 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 Infinia™ Total Knee System components are intended for cemented and single use only. The Freedom Infinia™ Cementless Femoral (CR and PS) Components and Porous Tibial Base Plates are additionally indicated for cementless biological fixation application.

VI. PERFORMANCE TESTING

The performance testing was leveraged from the testing performed on Freedom® Total Knee System Components. The cleared devices K082019, K090411, K091280, K111785, K131481, K150680, K182574, K192148, K241597, K243277, K251717 has the same device design, dimensions, materials, performance and functional characteristics. Therefore, the performance testing performed on the cleared Freedom® Total Knee System can be leveraged for the subject device.

VII. BIOCOMPATIBILITY

The biocompatibility tests are leveraged from the testing performed on Freedom® Total Knee System Components. The cleared devices K082019, K090411, K091280, K111785, K131481, K150680, K182574, K192148, K241597, K243277, K251717 has the same device design, dimensions, materials, performance and functional characteristics, manufacturing processes, packaging & sterilization as the subject devices. Therefore, the biocompatibility testing performed on the cleared® Total Knee System can be leveraged for the subject device.

VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION

There are no significant technological differences between the subject and predicate device. The subject devices Freedom Infinia™ Total Knee System are same as the predicate devices in terms of device design, dimensions, materials, performance and functional characteristics, manufacturing processes, packaging, sterilization, shelf life Intended Use and Indications for use. 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 is substantially equivalent to the proposed predicate devices.

IX. 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.