February 13, 2025

Maxx Orthopedics, Inc.
% Justin Gracyalny
Regulatory Affairs Manager
Secure BioMed Evaluations
7828 Hickory Flat Hwy, Suite 120
Woodstock, Georgia 30188

Re: K241597
Trade/Device Name: Freedom® Total Knee System - Porous Tibial Base Plate
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: January 17, 2025
Received: January 17, 2025

Dear Justin Gracyalny:

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)*

K241597

Device Name

Freedom® Total Knee System - Porous Tibial Base Plate

Indications for Use *(Describe)*

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® Porous Tibial Base Plate and Cementless Femoral Components are indicated for Cemented or Uncemented use. All other components are indicated for cemented 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.

K241597

510(k) SUMMARY:

Freedom® Total Knee System – Porous Tibial Base Plate

Date Prepared	February 13, 2025
Sponsor	Maxx Orthopedics Inc. 2460 General Armistead Ave, Suite 100 Norristown, PA 19403
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 Phone: 770-837-2681 Email: Regulatory@SecureBME.com
Trade Name	Freedom® Total Knee System – Porous Tibial Base Plate
Common Name	Knee Prosthesis
Product Code – Regulation Number	• MBH – Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis (21 CFR §888.3565) • JWH – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3560)
Primary Predicate	K182346 Exactech, Inc. TRULIANT Porous Tibial Tray
Reference Device(s)	K030623 Smith & Nephew Profix TKA System K090411 Maxx Orthopedics Inc. Freedom Metal Backed Tibial Component K171991 DJO Surgical, Inc. EMPOWR Porous Knee System K211221 Smith & Nephew, Inc. Porous Patella and Porous Tibia Baseplate K230321 Zimmer, Inc. Persona™ Personalized Knee System
Device Description	The Freedom® Porous Tibial Base Plate is a line extension of the Freedom® Total Knee System comprising of tibial base plate components for cemented or uncemented use in total knee arthroplasty. Freedom® Porous Tibial Base Plates are intended for use with existing, compatible Freedom® femoral and tibial liner components. Freedom® 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® 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.

Indications for Use Statement	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® Porous Tibial Base Plate and Cementless Femoral Components are indicated for Cemented or Uncemented use. All other components are indicated for cemented use only.

Comparison of Technological Characteristics

Device Characteristic	**Subject Device Maxx Orthopedics Inc. Freedom® Total Knee System – Porous Tibial Base Plate**	**Primary Predicate Device Exactech, Inc. TRULIANT Porous Tibial Tray K182346**
Intended Use	Total Knee Arthroplasty	Total Knee Arthroplasty
Manufacturing	Additive (EBM) and Subtractive	Additive (EBM)
Material	Ti-6Al-4V ELI per ASTM F3001	Ti-6Al-4V per ASTM F2924 / ASTM F136
Porous Coating	Yes	Yes
Base Plate Symmetry	Asymmetrical	Symmetrical
Sterilization	Implants: Provided sterile, SAL 10^{-6} Instruments: Provided non-sterile for end-user sterilization, SAL 10^{-6}	Implants: Provided sterile, SAL 10^{-6} Instruments: Provided non-sterile for end-user sterilization, SAL 10^{-6}
Packaging	Dual Tray Configuration	Dual Tray Configuration
Single Use Only	Yes	Yes
Prescription Use Only	Yes	Yes

Technological Characteristics

There are no significant technological differences between the subject and predicate device. The subject device uses similar materials, is a similar design, and achieves its intended use in an identical manner as the predicate and both devices are manufactured using similar additive manufacturing techniques. Minor differences in base plate geometry, symmetry, and sizing are addressed via performance testing and similarity to the reference devices (K171991, K211221, K230321). Minor differences in the indications for use do not introduce a new intended use when

compared to the predicate device or impact the safety and effectiveness of the device when used as labeled.

Non-Clinical Performance Testing Summary

All necessary testing has been performed for the subject device to assure substantial equivalence to the predicate device and to demonstrate the subject device performs as intended. All testing was performed on worst case implants or test coupons as dictated by the relevant performance standards. The following evaluations were conducted:

- Tibial Tray Fatigue Testing per ASTM F1800
- Residual Particle Characterization Testing per ASTM F1877
- Porous Surface Characterization Testing per ASTM F1854, ASTM F1160, ASTM F1044, ASTM F1978, ASTM F1147
- Sterilization per ISO 11137-2
- Endotoxin per AAMI ST72
- Biocompatibility per ISO 10993-1, ISO 10993-5

Results of the residual particle characterization were shown to be substantially equivalent to values presented in the literature for the reference device (K030623). Modular disassembly testing was leveraged from the reference device (K090411) as the subject device uses an identical tibial insert locking mechanism.

Conclusions

Based on the similarities of the intended use / indications for use, technological and functional characteristics, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.