November 19, 2024

Maxx Orthopedics, Inc.
Donald Guthner
Director, Regulatory Affairs
2460 General Armistead Avenue
Suite 100
Norristown, Pennsylvania 19403

Re: K243277
Trade/Device Name: Freedom® Medial Congruent Liner
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: October 16, 2024
Received: October 16, 2024

Dear Donald Guthner:

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)*

K243277

Device Name

Freedom® Medial Congruent Liner

Indications for Use *(Describe)*

The Freedom® Medial Congruent Liner consists of an ultra-high molecular weight polyethylene (UHMWPE) liner that is designed to be used with the Freedom® Total Knee Cruciate Retaining (CR) Femoral Components in the Freedom® Total Knee System. 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, and polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee join contour, particularly when there is patellofemoral erosion, dysfunction, and/or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods.

The Freedom® Medial Congruent Tibial Liner is intended for cemented use only. This device is 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.

maxx orthopedics

510(k) Summary

CONTACT DETAILS: 21CFR 807.92(a)(1)

Applicant Name:	Maxx Orthopedics, Inc.
Applicant Address:	2460 General Armistead Ave, Suite 100 Norristown, PA 19403 United States of America
Applicant Contact Telephone:	646-460-2984
Applicant Contact:	Mr. Donald Guthner
Applicant Contact Email:	Don.guthner@maxxortho.com

DEVICE NAME 21CFR 807.92(a)(2)

Device Trade Name:	Freedom® Medial Congruent Liner
Common Name:	Medial Congruent CR Tibial Liner
Classification Name:	Knee joint patellofemorotibial polymer/metal/polymer semi constrained cemented prosthesis
Regulation Number:	21 CFR 888.3560
Product Code(s)	JWH

LEGALLY MARKETED PREDICATE DEVICES 21CFR 807.92(a)(3)

Predicate #	**Predicate Trade Name**	**Product Code**
K182574	Freedom Ultracongruent CR Tibial Liner	JWH

DEVICE DESCRIPTION SUMMARY 21CFR 807.92(a)(4)

Freedom® 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 Freedom 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

INTENDED USE/INDICATIONS FOR USE 21CFR 807.92(a)(5)

The Freedom® Medial Congruent Liner consists of an ultra-high molecular weight polyethylene (UHMWPE) liner that is designed to be used with the Freedom® Total Knee Cruciate Retaining (CR) Femoral Components in the Freedom® Total Knee System. 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, and polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee join contour, particularly when there is patellofemoral erosion, dysfunction, and/or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.

• Knee fractures untreatable by other methods.
The Freedom® Medial Congruent Tibial Liner is intended for cemented use only. This device is for single use only.

INDICATIONS FOR USE COMPARISON 21CFR 807.92(a)(5)
The Indications for Use Statements are identical between the Subject Device and the Predicate Device.

TECHNOLOGICAL COMPARISON 21CFR 807.92(a)(6)

DEVICE DESCRIPTION AND COMPARISON TO CLEARED DEVICE
The Freedom® Medial Congruent Liner is intended for use with the currently available, FDA Cleared, Freedom® Total Knee Cruciate Retaining (CR) Femoral Component (K082019) as part of total knee replacement (TKR) surgery. Total knee replacement surgery is a procedure where worn, diseased, or damaged surfaces of the knee joint are removed and replaced with artificial surfaces. The MC Tibial insert will be a prescription product consisting of single use only, implantable devices for implanting into patients in an operating theatre by a qualified surgeon.

The devices are to be packaged and terminally sterilized by ethylene oxide. The packaging is to keep devices sterilized for 5 years. The packaging will be able to be opened easily in an operating theatre without instruments and in a manner that allows the implant to remain sterile.

The MC tibial inserts have been developed with the desire to achieve a medial stability of the CR femoral component while also providing posterior femoral rollback of the lateral condyle throughout a range of motion to provide the knee with a medial-pivoting motion, which more closely replicates natural motion. They possess an anterior buildup and a high level of conformity to the femoral condyle in the sagittal plane of the medial compartment to enable a high level of constraint and stability. Additionally, the lateral compartment features a decreased anterior and posterior lip as well as a decreased sagittal conformity to the lateral condyle of the CR femoral component to allow for mobility in the A/P aspect. The MC tibial inserts are designed to eliminate the need to remove bone for a PS box and allow for high flexion with the anterior buildup of the medial compartment to increase subluxation forces relative to more traditional CR tibial inserts.

The modular Freedom Knee tibial component is composed of a UHMWPE tibial insert inserted into a metal tibial tray. The MC tibial inserts will be used with the current tibial trays. The A/P and M/L aspect of the MC insert and UC insert are identical. The topographical footprints of the MC insert and the UC insert are also identical. The material and locking tab geometry of the MC tibial insert are identical to the current Freedom UC tibial insert. Therefore, the tibial insert inserts and disassembly forces with the tray can be considered the same for the MC tibial insert as for the UC tibial insert and no additional insertion and disassembly testing is needed.
A dimensional diagram of the bearing surfaces of the MC tibial inserts is included in this submission. Those dimensions integral to the compatibility of insert size with femoral size are shown to be the same for the MC tibial insert as the UC tibial insert. In addition, dimensions defining the insert thickness and the location of the most distal point of the tibial condyles are comparable between the MC and UC tibial inserts. The sizing and compatibility of the MC tibial inserts and the Freedom CR femoral components is therefore the same as for the existing UC tibial inserts and femoral components.

The Subject Device's articular surface is asymmetric in that its medial compartment and lateral compartment each feature different articular sagittal radii. The Subject Device differs from the Predicate Device in the

design of the medial anterior lip of the insert, in that it is slightly elevated with the desire to achieve a medial stability of the CR femoral component. The subject device's medial compartment also features an increased sagittal conformity at full extension with respect to the mating CR femoral component compared to that of the Predicate Device. The lateral compartment of the Subject Device features a decreased sagittal conformity compared to the Predicate Device while also featuring a decreased anterior and posterior buildup compared to the Predicate Device to enable greater A/P translation of the femoral component's lateral condyle throughout a range of motion.

NON-CLINICAL and/or CLINICAL TESTS SUMMARY AND CONCLUSIONS 21CFR 807.92(b)
The following tests were performed on the Subject Device and compared to the Predicate Device:

- Tibiofemoral Range of Motion (ASTM F2083 6.2.3)
    - Simulated Computer-Aided-Design software determined the range of motion (maximum flexion angle) of the Subject Device was equivalent to the Predicate Device.

- Tibiofemoral Constraint Characterization (ASTM F1223 and F2083)
    - The purpose of this study was to characterize the anterior/posterior (A/P), medial/lateral (M/L), and internal/external constraint of the articular surface through the required various degrees of flexion as compared to the Predicate Device. The results satisfied the pre-established benchmark performance in comparison to the Predicate Device.

- Tibiofemoral Contact Area and Contact Pressure (ASTM 2083 6.2.2)
    - Determined the contact area and contact pressure of the articular surface of the Subject Device and compared with the previously recorded results of the Predicate device at the required flexion angles and orientations. The contact area and contact pressure was found to be equivalent throughout a range of motion compared to the Predicate Device.

Conclusion: The Freedom® Medial Congruent Liner design does not raise any different questions of safety or effectiveness. The intended use, indications for use, and technological characteristics, of the Freedom® Medial Congruent Liner are substantially equivalent to the predicate Freedom Ultracongruent CR Tibial Liner.