August 7, 2026

Maxx Orthopedics, Inc.
Asawari Hare
Regulatory Associate
2460 General Armistead Ave. #100
Norristown, Pennsylvania 19403

Re: K261563
Trade/Device Name: Freedom Total Knee System (E-Poly Tibial Liners)
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Codes: JWH, OIY
Dated: May 11, 2026
Received: May 11, 2026

Dear Asawari Hare:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2026.08.07 10:00:58 -04'00'

for Lixin Liu, PhD
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)*
K261563

Device Name
Freedom Total Knee System (E-Poly Tibial Liners)

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, Primary PCK Components, and Metaphyseal Cones only).

The Freedom Porous Tibial Base Plate, Cementless Femoral Components, and Metaphyseal Cones are indicated for Cemented or Uncemented use. All other components are indicated for cemented use only.

The Freedom Metaphyseal Cones are additionally indicated for use in addressing tibial bone voids and/or metaphyseal reconstruction.

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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510(k) #:

510(k) Summary

Prepared on: 2026-07-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Maxx Orthopedics, Inc.
Applicant Address	2460 General Armistead Ave #100 Norristown PA 19403 United States
Applicant Contact Telephone	6177087388
Applicant Contact	Ms. Asawari Hare
Applicant Contact Email	asawari.hare@maxxortho.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Freedom Total Knee System (E-Poly Tibial Liners)
Common Name	Total Knee Replacement System (with modified tibial liners)
Classification Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number	888.3560
Product Code(s)	JWH, OIY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K250382	Freedom Total Knee System: All-Poly Tibial Plate	JWH
K082019	Freedom All-poly Tibial Baseplate	JWH
K090411	Freedom Metal Tibial baseplate	JWH
K182574	Freedom UC Tibial Liner	JWH
K243277	Freedom MC Tibial Liner	JWH

Legally Marketed Reference Devices

K192989	Libertas E-XLPE Modular Liners	OQI

Device Description Summary

21 CFR 807.92(a)(4)

The E-Poly Tibial implants have been developed with the desire to expand upon the already clinically successful Freedom® Total Knee System by introducing a crosslinked material. The implants will retain the exact design features and geometries of the All-Poly Tibial implant system (K082019, K250382) and the modular, metal-backed systems (K090411, K182574, K243277). By introducing Vitamin E crosslinks into the material, this removes excess radicals in the polymer that contributes to oxidation. These versions will be manufactured from GUR 1020-E UHMPE containing 0.1% Vitamin E.

The new Tibial implants are designed to work the same as the existing All-Poly and modular, metal-backed Freedom® system components with identical profiles and size ranges. The E-Poly Tibial implants will come in multiple articular surface types. The Cruciate-Retaining articular surface is identical to those cleared in K082019, the Posterior-Stabilized articular surface is identical to those cleared in

K082019, the Ultracongruent articular surface is identical to those cleared in K182574, and the Medial Congruent articular surface is identical to those cleared in K243277. This will provide the surgeons with the full portfolio of Freedom® bearing surfaces with a higher wear resistance. Surgeons will be able to use the same instruments/surgical technique to the Freedom® Total Knee System.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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, Primary PCK Components, and Metaphyseal Cones only).

The Freedom Porous Tibial Base Plate, Cementless Femoral Components, and Metaphyseal Cones are indicated for Cemented or Uncemented use. All other components are indicated for cemented use only.

The Freedom Metaphyseal Cones are additionally indicated for use in addressing tibial bone voids and/or metaphyseal reconstruction.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use are the same.

Technological Comparison

21 CFR 807.92(a)(6)

The E-Poly Tibial implants have been developed with the desire to expand upon the already clinically successful Freedom® Total Knee System by introducing a Vitamin E crosslinked material. The implants will retain the exact design features and geometries of the All-Poly Tibial implant system (K082019, K250382) and the modular, metal-backed systems (K090411, K182574, K243277). The implants will be manufactured in GUR 1020-E UHMPE containing 0.1% Vitamin E; this is equivalent to the material in reference device K192989 for the Libertas E-XPLE Modular Liners. This combination will maintain the previous design outputs of the Freedom Knee System while eliminating the oxidation causing radical in the GUR 1020.

The new Tibial implants are designed the same as the existing All-Poly and modular, metal-backed Freedom® system components with identical profiles, size ranges, and articular surface types. The Cruciate-Retaining articular surface is identical to those cleared in K082019, the Posterior-Stabilized articular surface is identical to those cleared in K082019, the Ultracongruent articular surface is identical to those cleared in K182574, and the Medial Congruent articular surface is identical to those cleared in K243277. This will provide the surgeons with the full portfolio of Freedom® bearing surfaces. Surgeons will be able to use the same instruments/surgical technique to the Freedom® Total Knee System.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Range of Motion (ROM) analysis was completed separately for the Cruciate Retaining (CR), Posterior Stabilizing (PS), Medial Congruent (MC), and Ultra Congruent (UC) systems in previous submissions. Implant geometry is the only driving factor in range of motion, therefore change in material was not considered in performance and no new ROM testing was required. Reference documentation for ROM on the CR, PS, and UC was used. In prior submissions, it was determined that the MC articulating surface does not create a new worst case and was therefore validated through the UC surface testing.

Contact pressure/stress analysis was completed separately for the CR, PS, MC, and UC systems in previous submission. Implant geometry is the only driving factor in contact pressure, therefore change in material was not considered in performance and no new contact pressure/stress testing was required.

For wear resistance, implant geometry and material are considered as the driving factors. As implant geometry was proven to be identical to the previously approved Freedom Knee System, material was taken as the primary consideration in wear resistance. Wear testing was, previously, completed on the E-Poly Metal backed PS implant (following ISO 14243-1:2009 and 14243-2:2009). To evaluate material change, the PS E-Poly Implant was reported on in 838-150918-20-657 under the same standard. These tests primarily looked at mean wear rate (mg/million cycles) and wear. In comparison, the E-Poly PS Tibias showed lower wear rates and wear. As material was the isolated difference between the two reports, the comparison can be extrapolated to all other articulating surfaces.

The E-Poly Tibial Implants were determined to be within the scope of the reference Range of Motion Validations completed on the Freedom Knee CR, PS, UC, and MC implant families.

The E-Poly Tibial Implants were determined to be within the scope of the referenced Contact Pressure and Stress Validation completed on the Freedom Knee CR, PS, UC, and MC implant families.

Due to a comparison between the approved PS system wear testing and the E-Poly PS wear testing, it was determined that the E-Poly Implants do not create a new worst case for wear resistance. Therefore, they fall within the scope of the wear resistance validations completed on the Freedom Knee System.

All E-Poly Tibial Implant were found to be substantially equivalent to the previously validated implants and are thus verified and validated for clinical use.