



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Maxx Orthopedics, Incorporated
Ms. Gabriela Gottlieb
Regulatory Affairs Manager
531 Plymouth Rd., Suite 526
Plymouth Meeting, Pennsylvania 19462

June 26, 2015

Re: K150680

Trade/Device Name: Freedom[®] Cementless Femoral Components

Regulation Number: 21 CFR 888.3565

Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: MBH

Dated: March 16, 2015

Received: March 18, 2015

Dear Gabriela Gottlieb:

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 (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. 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](#).

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: Freedom® Cementless Femoral Components

Indications for Use:

The Freedom® Cementless Femoral Components are designed to be used as a part of the Freedom® Total Knee System, and 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, and/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, Freedom Stemmed Tibial Components and Freedom PCK Components are indicated for cemented fixation. Only Cementless Femoral (CR and PS) components with porous coating are additionally indicated for cementless biological fixation application.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 13**510(k) Summary****Submitter:**

Maxx Orthopedics, Inc.
531 Plymouth Rd #526
Plymouth Meeting, PA 19462

Date of Summary: June 25, 2015**Establishment Registration Number:** 3007311878**Contact Person:**

Gabriela Gottlieb
Manager, Regulatory and Clinical Affairs
Phone: 215-606-7418
Email: gabriela.gottlieb@maxxortho.com

Alternate Contact:

Nach Dave
Director, Regulatory and Clinical Affairs
Phone: 732-718-1385
Email: nach.dave@maxxortho.com

Device Information:

Proprietary Name: Freedom® Cementless Femoral Components
Common/Usual Name: Cementless Femoral Components
Classification Name: Knee Joint Patelofemorotibial Metal/Polymer porous-coated
Cementless prosthesis
Regulation Number: 21 CFR 888.3565
Regulatory Class: Class II
Product Code: MBH

Identification of Predicate Device(s):

The Freedom® Cementless Femoral Components are similar to the following commercially available devices in regards to the fundamental scientific technology, material composition and intended use:

Device Name	Type	Device Class	Product Code	Regulation Number	510(k) number
Freedom Total Knee system	Primary	II	JWH	21 CFR § 888.3560	K082019 K091280 K131481
Optetrak Logic® Porous Femoral Component	Reference	II	MBH	21 CFR § 888.3565	K140302

Device Description:

The Cementless Femoral Components (“Components”) are intended for use with the currently available Freedom® Total Knee System 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 Components will be prescription products consisting of single use only, implantable devices for implanting into patients in an operating theatre by a qualified surgeon.

Intended Use:

The Freedom® Cementless Femoral Components are designed to be used as a part of the Freedom® Total Knee System, and 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, and/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, Freedom Stemmed Tibial Components and Freedom PCK Components are indicated for cemented fixation. Only Cementless Femoral (CR and PS) components with porous coating are additionally indicated for cementless biological fixation application.

Substantial Equivalence for Technological Characteristics:

The proposed Maxx Orthopedics’ Freedom® Cementless Femoral Component and the primary predicate device are identical in that they consist of same geometric design, material of composition, and intended use. The proposed components are also the same in fundamental scientific technology as the referenced predicate device (porous coating). The only difference is the device’s operating mechanism, which is expanded to give the Surgeon the option to apply implant without cement.

Both the proposed Freedom® Cementless Femoral Components and the predicate devices have been designed to mimic the normal knee geometry. Both the proposed and predicate devices are compatible with left and right configurations and available in a variety of sizes that are intended to mimic normal human anatomy. Both the proposed and predicate devices are made of biocompatible materials and are identical in technological design and materials.

Performance Testing:

Mechanical and functional testing described in Section 8 of this 510(k) submission demonstrates that the Freedom® Cementless Components are mechanically and functionally equivalent to the parent Freedom® Total Knee System. The evaluations were performed in accordance with the Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Cementless Prostheses; Guidance for Industry and FDA. The results were found to be equivalent to the legally marketed predicate device.

Test Name	Test #	Objective
Stereological Evaluation	TR-15-01	The purpose of this study was to determine (1) percent porosity, (2) pore size (line length intercept), and (3) coating thickness of CoCr coupons coated and sintered with three layers of -40/+60 mesh CoCr powder. The interconnection of porosity was also examined on all coupons. The coating technique utilized in this study is identical to the coating technique used for specified medical implants.
Static Shear and Tensile Testing	TR-15-02	The purpose of this study was to determine (1) static shear strength, and (2) static tensile strength of CoCr coupons coated and sintered with -40/+60 mesh CoCr powder. The coating technique utilized in this study is identical to the coating technique used for specified medical implants.
Abrasion Testing	TR-15-03	The purpose of this study was to determine the abrasion resistance of CoCr plates coated and sintered with three layers of -40/+60 mesh CoCr irregular-shaped beads. The plates and the -40/+60 bead powder conform to ASTM F75. The coating technique utilized in this study was identical to the coating technique used for ASTM F75 implants. Abrasion testing was conducted at the Orchid Orthopedic Solutions facility in Detroit, MI).
Shear fatigue testing	TR-15-04	The purpose of this study was to determine shear fatigue strength of ASTM F75 CoCr coupons coated and sintered with three layers of -40/+60 mesh CoCr powder. The coating technique utilized in this study is identical to the coating technique used for specified medical implants.

Clinical Testing:

Clinical Testing was not required for these components to support substantial equivalence determination.