510(k) Summary
for
Freedom® Total Knee Cruciate Retaining (CR) Femoral Component

1. SPONSOR

Maxx Orthopedics, Inc.
2260 Butler Pike
Suite 100
Plymouth Meeting, PA 19462

SEP 2 5 2009

Contact Person: Nach Dave
Telephone: 732-718-1385

Date Prepared: April 30, 2009

2. DEVICE NAME

Proprietary Name:	Freedom® CR Femoral Component
Common/Usual Name:	Cruciate Retaining Total Knee Replacement
Classification Name:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis -21 CFR §888.3560

3. PREDICATE DEVICES

- Freedom Total Knee system subject of K082019
- Osteonics Scorpio Cruciate Retaining Total Knee System, subject of K974566

4. DEVICE DESCRIPTION

The Maxx Orthopedics' Freedom® CR Femoral Component is compatible with the Maxx Orthopedics Freedom® Total Knee System subject of K082019 and the Metal Backed Tibial Component subject of K090411. The Maxx Orthopedics' Freedom® Total Knee System subject of K082019 is comprised of a femoral component, tibial component and patella component.

The proposed Freedom® CR Femoral Component consist of a cobalt-chromium molybdenum (CoCrMo) component that is designed to be used with the Freedom® Total Knee System described in K082019 and the Freedom Metal Backed Tibial Component subject of K090411. The Maxx Orthopedics' Freedom® Total Knee System subject of K082019 is comprised of a femoral component (posterior stabilizing), an all-poly tibial

component, and a patellar component. The Freedom Metal Backed Tibial Component subject of K090411 consists of a metal backed tibial component and polyethylene insert. The proposed CR Femoral Component will provide the surgeon with an alternative femoral component in the event that the surgeon prefers to use a CR component rather than the PS component with the Freedom® Total Knee System. In addition, a second metal backed tibial component was cleared for use with the Freedom Total Knee System under K090411. The proposed CR Femoral Component and a (UHMWPE) insert will be used in place of the PS Femoral component with the Freedom® Total Knee System.

The CR Femoral Component of the Freedom® Total Knee System CR is designed to replace the articulating surface of the distal femur. The cruciate retaining femoral component is utilized when total knee replacement is indicated, and accommodates the posterior cruciate ligament if it is present.

5. INTENDED USE

The Freedom® CR Femoral Component consists of a cobalt-chromium molybdenum (CoCrMo) component that is designed to be used with the Freedom Total Knee System. The Maxx Orthopedics' Freedom® Total Knee System is indicated for patients with severe knee pain and disability due to:

- 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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The proposed Maxx Orthopedics' Freedom® CR Femoral Component and the predicate devices are identical in that they all consist of cobalt-chromium molybdenum (CoCrMo) material and are available in right and left cruciate retaining configurations.

Both the proposed component and the predicate devices have been designed to mimic the normal knee geometry. Both the proposed and predicate devices are available in a variety of sizes that are intended to mimic normal human anatomy. The articulating

surface of the proposed Maxx Orthopedics Freedom® femoral and tibial components, are similar to the articulating surface of the predicate systems and are functionally equivalent devices. Both the proposed and predicate devices are made of biocompatible materials and are technological designed and identical in materials.

7. PERFORMANCE TESTING

Mechanical and functional testing described in K082019, K090411 and in Section 8 demonstrates that the Freedom® CR Femoral Component are mechanically and functionally similar to the parent Freedom UHMWPE Tibial Component and other legally marketed knee systems. Evaluations were performed to determine the material and mechanical characteristics of the Maxx Orthopedics' Freedom® CR Femoral Component and the Freedom® Total Knee System according to the Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA. The verification and validation testing have been performed which demonstrate that the CR Femoral Component functions as intended and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

SEP 25 2009

Maxx Orthopedics, Inc.
c/o Ms. Mary McNamara-Cullinane
Senior Regulatory Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K091280
Trade/Device Name: FREEDOM® Total Knee Cruciate Retaining (CR) Femoral Component
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: July 24, 2009
Received: August 6, 2009

Dear Ms. McNamara-Cullinane:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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

CFR Part 807); labeling (21 CFR Part 801); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K091280

Device Name: Maxx Orthopedics' Freedom® Total Knee Cruciate Retaining (CR) Femoral Component

Indications for Use:

The Freedom® Total Knee Cruciate Retaining (CR) Femoral Component consists of a cobalt-chromium molybdenum (CoCrMo) femoral component designed to be used with the Freedom® Total Knee System, and the Freedom® Total Knee Metal Backed Tibial Components. 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, and/or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods

The Freedom® Total Knee Cruciate Retaining (CR) Femoral Component is intended for cemented use only. This device is for single use only.

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)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091280