

K093552

MAR - 4 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the EVOLUTION™ MP Total Knee System.

Submitted By: Wright Medical Technology, Inc.

Date: November 16, 2009

Contact Person: Ryan Ross
Regulatory Affairs Specialist II

Proprietary Name: EVOLUTION™ MP Total Knee System

Common Name: Total Knee System

Classification Name and Reference: 21 CFR 888.3560 Knee joint Patellofemorotibial
Polymer/Metal/Polymer Semi-Constrained
Cemented Prosthesis Class II

21 CFR 888.3530 Knee joint Femorotibial
Metal/Polymer Semi-Constrained Cemented
Prosthesis Class II

Subject Product Code and Panel Code: Orthopedics/87/ JWH, HRY

DEVICE INFORMATION

A. Intended Use

The EVOLUTION™ MP Total Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. inflammatory degenerative joint disease including rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and
5. treatment of fractures that are unmanageable using other techniques.

The EVOLUTION™ MP Total Knee System is for cemented use only.

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B. Device Description

The design features of the EVOLUTION™ MP Total Knee System are summarized below:

- Femoral components manufactured from Cobalt Chrome Alloy
- Femoral component sizes 1 - 8, left and right
- Intended to be used with currently available patella components
- Tibial inserts manufactured from UHMWPE
- Tibial insert sizes 1 – 8, left and right
- Tibial insert thickness: 10, 12, 14, 17, 20, 24mm
- Tibial bases manufactured from Cobalt Chrome Alloy
- Tibial base sizes 1 – 8, left and right
- Asymmetric

C. Substantial Equivalence Information

The indications for use of the EVOLUTION™ MP Total Knee System are identical to the previously cleared predicate devices. The design features and materials of the subject devices are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicate devices. The safety and effectiveness of the EVOLUTION™ MP Total Knee System are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

MAR - 4 2010

Wright Medical Technology, Inc.
% Mr. Ryan Ross
Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K093552

Trade/Device Name: EVOLUTION™ MP Total Knee System

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained
cemented prothesis

Regulatory Class: II

Product Code: JWH, HRY

Dated: March 3, 2010

Received: March 4, 2010

Dear Mr. Ross:

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 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 (301) 796-7100 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

K093552

Indications for Use

510(k) Number (if known):

Device Name: EVOLUTION™ MP Total Knee System

Indications For Use:

The EVOLUTION™ MP Total Knee System is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

1. noninflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. inflammatory degenerative joint disease including rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and
5. treatment of fractures that are unmanageable using other techniques.

EVOLUTION™ MP Total Knee System non-porous components are for cemented use only.

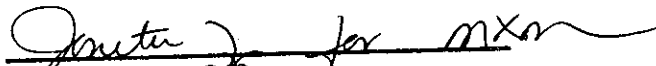
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

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