

K100973

AUG 10 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™ Unicondylar Knee System.

**Submitted By:** Wright Medical Technology, Inc.  
5677 Airline Rd, Arlington TN, 38002  
(800) 238-7188

**Date:** August 2, 2010

**Contact Person:** Danielle Mueller  
*Regulatory Affairs Specialist II*

**Proprietary Name:** EVOLUTION™ Unicondylar Knee System

**Common Name:** Unicondylar Knee System

**Classification Name and Reference:** 21 CFR 888.3530 Knee joint Femorotibial  
Metal/Polymer Semi-Constrained Cemented  
Prosthesis Class II  
21 CFR 888.3520 Knee joint Femorotibial  
Metal/Polymer Non-Constrained Cemented  
Prosthesis Class II

**Subject Product Code and Panel Code:** Orthopedics/87/ HRY, HSX

**Predicate Devices:** ADVANTIM® Unicondylar Knee System  
ADVANCE® Unicondylar Knee System  
ADVANCE® Ultra-Congruent Tibial Insert  
EVOLUTION™ MP Total Knee System  
510(k)s: K881779, K012591, K014171, K030193,  
K972770, K093552

**DEVICE INFORMATION**

**A. Intended Use**

The EVOLUTION™ Unicondylar 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. correction of functional deformity;
3. revision procedures where other treatments or devices have failed: and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION™ Unicondylar Knee System is indicated for patients with unicompartmental joint disease secondary to the above indications with or without valgus, varus, or flexion deformities where all ligaments are intact.

The EVOLUTION™ Unicondylar Knee System is for cemented use only.

## **B. Device Description**

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

- Femoral components manufactured from Cobalt Chrome Alloy
- Femoral component sizes 1 – 5, Resurfacing- or Resection-based
  
- Tibial inserts manufactured from UHMWPE
- Tibial insert: Universal, sizes 1 – 5
- Tibial insert: Conforming, sizes 1 – 5, left and right
- Tibial component thickness: 8, 9, 10, 11, 12mm
  
- Tibial bases manufactured from Titanium Alloy
- Tibial base sizes 1 – 5, left and right
  
- All-poly tibial components manufactured from UHMWPE
- All-poly Universal: sizes 1 – 5, left and right
- All-poly Conforming: sizes 1 – 5, left and right
- All-poly tibial component thickness: 7, 8, 9, 10, 11, 12mm

The EVOLUTION™ Unicondylar Knee System was evaluated via mechanical testing and engineering analyses; including static stability, contact area, lock detail, femoral component strength, range of motion, and wear testing. A review of these results indicates that the EVOLUTION™ Unicondylar Knee System components are equivalent to predicate devices and are capable of withstanding expected *in vivo* loading without failure.

## **C. Substantial Equivalence Information**

The indications for use of the EVOLUTION™ Unicondylar 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™ Unicondylar 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 -WO66-G609  
Silver Spring, MD 20993-0002

Wright Medical Technologies, Inc.  
% Ms. Danielle Mueller  
Regulatory Affairs Specialist  
5677 Airline Road  
Arlington, Tennessee 38002

AUG 10 2010

Re: K100973

Trade/Device Name: EVOLUTION Unicondylar Knee System  
Regulation Number: 21 CFR 888.3530  
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented  
prosthesis  
Regulatory Class: Class II  
Product Code: HRY, HSX  
Dated: July 15, 2010  
Received: July 16, 2010

Dear Ms. Mueller:

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.

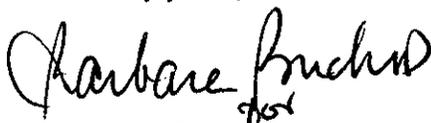
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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 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

K100973

**Indications for Use**

510(k) Number (if known):

AUG 10 2010

Device Name: EVOLUTION™ Unicondylar Knee System

Indications For Use:

**The EVOLUTION™ Unicondylar 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. correction of functional deformity;
3. revision procedures where other treatments or devices have failed: and treatment of fractures that are unmanageable using other techniques.

The EVOLUTION™ Unicondylar Knee System is indicated for patients with unicompartmental joint disease secondary to the above indications with or without valgus, varus, or flexion deformities where all ligaments are intact.

The EVOLUTION™ Unicondylar Knee System is 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)

*Jonita J. for MVM*  
 \_\_\_\_\_  
 (Division Sign Off)  
 Division of Surgical, Orthopedic,  
 and Restorative Devices

Page 1 of  1

510(k) Number  K100973