510(k) Summary

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 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the EVOLUTION® MP Adaptive PS Tibial Insert.

(a)(1) Submitted By:	Wright Medical Technology, Inc. 5677 Airline Rd Arlington, TN 38002 (901) 867-4146
Date:	OCT 2 3 2013 June 7, 2013
Contact Person:	Theresa Leister *Regulatory Affairs Manager*
(a)(2) Proprietary Name of Modified Device:	EVOLUTION® MP Adaptive PS Tibial Insert
Common Name:	Tibial Base Insert
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
(a)(3) Predicate Devices:	EVOLUTION® MP Total Knee System (K093552) EVOLUTION® MP Adaptive CS Insert (K113325)

(a)(4) Device Description

The purpose of this submission is to introduce a new EVOLUTION® MP Adaptive PS Tibial Insert that allows use of a posterior stabilized femoral component from the EVOLUTION® MP Total Knee System with a tibial base from the ADVANCE® Knee System.

(a)(5) Indications for Use
The EVOLUTION® MP Adaptive PS Insert 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 treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Total Knee System is for cemented use only.

(a)(6) Technological Characteristics of the Device
The indications for use of the EVOLUTION® Adaptive PS Tibial Insert are identical to the predicate devices. The lock detail of the EVOLUTION® Adaptive PS Tibial Insert is identical to that of the predicate EVOLUTION® Adaptive CS Tibial Insert. The design features are substantially equivalent to those of the predicate devices. The subject device allows use of a femoral component from the EVOLUTION® Total Knee System with a tibial base from the ADVANCE® Knee System. The design features of the EVOLUTION® Adaptive CS Insert are summarized below:

- Tibial inserts manufactured from UHMWPE
- Available in 7 sizes, left and right
- Tibial insert thickness: 10 – 20mm

The EVOLUTION® Adaptive PS Insert was evaluated via engineering analyses for static stability, contact area, wear, post strength, and range of motion. The analysis determined that the subject device does not present a new worst case as compared to the predicate devices; therefore, no additional testing was performed.

(b)(1) Nonclinical Testing
Nonclinical testing was not provided for the subject devices.

(b)(2) Clinical Testing
Clinical data was not provided for the subject devices.

(b)(3) Conclusions
The indications for use of the EVOLUTION® Adaptive PS Tibial Insert are identical to the predicate devices. The design features are substantially equivalent to those of the predicate devices. The fundamental scientific technology of the modified device has not changed relative to the predicate devices. The safety and effectiveness of the EVOLUTION® MP Adaptive PS Insert are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 23, 2013

Wright Medical Technology, Incorporated
Ms.Theresa Leister
Regulatory Affairs Manager
5677 Airline Road
Arlington, Tennessee 38002

Re: K131679
Trade/Device Name: EVOLUTION® MP Adaptive PS Insert
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, HRY
Dated: September 23, 2013
Received: September 25, 2013

Dear Ms. Leister:

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 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. 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,

for Erin D. Keith

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

Enclosure

Indications for Use

510(k) Number (if known): K131679

Device Name: EVOLUTION® MP Adaptive PS Insert

Indications For Use:

The EVOLUTION® MP Adaptive PS Insert 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 treatment of fractures that are unmanageable using other techniques.

The EVOLUTION® Total Knee System is for cemented use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices