K122985

OCT 2 6 2012

B. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Columbus REVISION Knee System
October 24, 2012

COMPANY: Aesculap® Implant Systems, LLC
3773 Corporate Parkway
Center Valley, PA 18034

ESTABLISHMENT REGISTRATION NUMBER: 3005673311

CONTACT: Julie Tom Wing
610-984-9147 (phone)
610-791-6882 (fax)
Julie.TomWing@aesculap.com

DEVICE

TRADE NAME:	REVISION
COMMON NAME:	Columbus REVISION Knee System
DEVICE CLASS:	CLASS II
PRODUCT CODE:	JWH
REGULATION NUMBER:	888.3560
CLASSIFICATION NAME:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-constrained Cemented Prosthesis

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the modification to Columbus REVISION Knee System remains substantially equivalent to Aesculap Implant Systems Columbus REVISION Knee System originally cleared in 510(K) K083772.

DEVICE DESCRIPTION

The cemented Columbus REVISION Knee System is a semi-constrained cemented prosthesis system. The system offers femoral and tibial augments as well as stems to provide options for use during reconstructive surgery, particularly revision cases. The system is manufactured from CoCrMo with the exception of the tibial "gliding surfaces" which are manufactured from UHMWPE and the tibial mask which is made of PEEK. The system is made up of numerous components available in various sizes. All components are sterile and for single use only. All components manufactured from CoCrMo are also available with a ZrN (Zirconium nitride) coating which has been cleared in Aesculap Columbus AS Knee submission (K071220) and described in cleared Columbus Revision submission (K083772).

INDICATIONS FOR USE

The Columbus REVISION Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity, or dysfunction persist, and for patients suffering from corrective valgus or varus deformity and moderate flexion contracture.
The Columbus REVISION Knee System is designed for use with bone cement.

TECHNOLOGICAL CHARACTERISTICS (Compared to the Predicate)

The entire Columbus REVISION Knee System was cleared under K083772.
The fundamental scientific technology and materials for the Columbus REVISION Knee System remain the same. The only difference is a design modification of the posterior stabilizing (PS) tibial post of the medium constraint (MC) and high constraint (HC) gliding surfaces (inserts).

PERFORMANCE DATA

Customized endurance testing based on ASTM F 2722-08 was performed on Aesculap Implant Systems Columbus REVISION tibial gliding surfaces, tibial post and fixation screw for 10 million cycles as a result of the risk assessment.
The results were found to be similar to the legally marketed Columbus REVISION Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Aesculap Implant System, Incorporated
% Ms. Julie Tom Wing
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

OCT 26 2012

Re: K122985
Trade/Device Name: Columbus REVISION Knee System
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: September 20, 2012
Received: September 26, 2012

Dear Ms. Wing:

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

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K122985

Device Name: Columbus REVISION Knee System

Indications for Use:

The Columbus REVISION Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

The Columbus REVISION Knee System is designed to for use with bone cement.

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(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

510(k) Number K122985