K083772 #1/2

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Columbus Revision Knee System
December 18, 2008

JUN - 4 2009

COMPANY: Aesculap Implant Systems®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Lisa M. Boyle
610-984-9274 (phone)
610-791-6882 (fax)

TRADE NAME: REVISION

COMMON NAME: Columbus Revision Knee System

CLASSIFICATION NAME: Prosthesis, Knee, Patellofemorotibial, Semiconstrained, Cemented, Polymer/Metal/Polymer

REGULATION NUMBER: 888.3560

PRODUCT CODE: JWH

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems®, Inc. believes that the Columbus Revision Knee System is substantially equivalent to:

- Aesculap's Columbus Total Knee System CR/PS (K022672/K030367),
- Zimmer's NexGen Complete Knee Solution Legacy Constrained Condylar Knee (K960279)

DEVICE DESCRIPTION

The cemented Columbus Revision Knee System is a fixed prosthesis system that is available with one femoral design, the Posterior Stabilizing (PS) which offers stabilization if the ligament (PCL) is absent, weakened, or sacrificed during implantation. The system is manufactured from CoCrMo with the exception of the tibial "gliding surfaces" which are manufactured from UHMWPE. The complete system (femoral and tibial) makes up of numerous component available in various sizes. All components are sterile and for single use only.

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.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap Implant Systems® Columbus Revision Knee System are offered in a similar range of shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the

- "Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses", and
- "Class II Special Controls Guidance Document for Knee Joint Patellofemorotibial & Femorotibial Metal/Polyer Porous-Coated Uncemented Prostheses: Guidance for Industry and FDA."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2009

Aesculap Implant Systems, Inc.
% Ms. Lisa Boyle
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K083772
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: May 29, 2009
Received: June 2, 2009

Dear Ms. Lisa Boyle:

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 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/cdrh/comp/ 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K083772

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)

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

510(k) Number K083772