SEP 14 2007

K071499

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

Columbus (CR) Total Knee System
(MIOS CR/PS Tibial Tray)
May 31, 2007

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

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

TRADE NAME: Columbus Total Knee System MIOS CR/PS Tibial Tray

COMMON NAME: Total Knee System

CLASSIFICATION NAME: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

REGULATION NUMBER: 888.3560

PRODUCT CODE: JWH

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems Inc. believes that the Columbus Total Knee System MIOS CR/PS Tibial Tray is substantially equivalent to Aesculap Implant Systems Inc. Columbus Total Knee System (K022672), Howmedica Osteonics Scorpio Low Profile Tibial Tray (K032829), and Zimmer's Millar/Galante Precoated Total Knee (K853661).

DEVICE DESCRIPTION

The Columbus MIOS CR/PS tibial tray is a sterile, single-use device that is intended to be used with the previously cleared femoral component, insert, patella, and attachment mechanism of the Columbus (CR) Total Knee System or with the femoral component and insert of the Columbus (PS) Total Knee System.

INDICATIONS FOR USE

The Columbus (CR) Total 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 Knee (CR) is designed for use with bone cement.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The MIOS CR/PS tibial tray is offered in similar shapes and sizes as the predicate devices. The base material used for the Aseculap Implant Systems device is the same as that used to manufacture the predicate devices. The only difference is a PMMA Nano-Bond surface pretreatment to the CoCrMo implants. The materials used in the PMMA Nano-Bond surface pretreatment are commonly used on other medical 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All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable.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 Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements"
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components", and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMPE) Used in Orthopedic Devices" was completed where applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2007

Aesculap Implant Systems Inc.
% Ms. Kathy A. Racosky
Regulatory Affairs Specialist
3773Corporate Parkway
Center Valley, PA 18034

Re: K071499
Trade/Device Name: Columbus Total Knee System MIOS CR/PS Tibial Tray
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: August 20, 2007
Received: August 21, 2007

Dear Ms. Racosky:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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:_____

Device Name: Columbus (CR) Total Knee System

Indications for Use:

The Columbus (CR) Total 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 Knee is designed 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)

Barbara Bradley for MRM ~~Concurrence~~ of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K071499