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

FEB 6 2006

Columbus (CR) Total Knee System
December 1, 2005

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
800-258-1946 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

TRADE NAME: Columbus (CR)Total Knee System

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®, Inc. believes that the Columbus (CR)Total Knee System additions are substantially equivalent to Aesculap's Columbus Total Knee System (K022672), Smith & Nephew's revision knee system (K043440) and PLUS Orthopedic's VKS/TC Plus revision knee (K032215), PLUS Orthopedic's RT-Plus Solution and RT-Plus Modular Knee (K023667), and Howmedica Osteonics's Tibial Tray Screw Hole Plugs (K032479).

DEVICE DESCRIPTION

The cemented Columbus (CR)Total Knee System additions include a CRA/PSA tibial tray and hemispacers, commonly known as wedges. The CRA/PSA tibial tray and wedges can be used with the existing femoral component, insert, patella and attachment mechanism of the Columbus (CR) Total Knee System cleared via K022672 or with the femoral component and insert of the Columbus (PS) Total Knee System cleared via K030367. The CRA/PSA tibial tray and wedges are manufactured from CoCrMo.

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 CRA/PSA tibial tray and wedges are offered in similar in shapes and sizes as the predicate devices. The material used for the Aseculap 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All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable.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 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

FEB 6 2006

Ms. Kathy A. Racosky
Regulatory Affairs Associate
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K053390
Trade/Device Name: Columbus (CR) Total Knee System
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: January 12, 2006
Received: January 13, 2006

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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting 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: K053390

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 (CR) is designed for use with bone cement.

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

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 General, Restorative,

and Neurological Devices

510(k) Number K053390