DEC 13 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

COLUMBUS (CR) TOTAL KNEE SYSTEM

November 10, 2002

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Joyce Kilroy, Director of Regulatory Affairs/Quality Assurance
800-258-1946 (phone)
610-791-6882 (fax)
joyce.kilroy @ aesculap.com (email)

TRADE NAME: Columbus (CR) Total Knee System

COMMON NAME: Total Knee System

DEVICE CLASS: Class II

PRODUCT CODE: JWH

CLASSIFICATION: 888.3560

REVIEW PANEL: Orthopedics

INTENDED USE

The Columbus (CR) Total Knee System is intended 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 persists, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

The Columbus Knee is designed for use with bone cement.

DEVICE DESCRIPTION

The cemented Columbus (CR) Total Knee System is available with one femoral design, the Cruciate Retaining (CR) which retains the ligament (PCL) during implantation. The design of the femoral component and tibial plateau (tray) are manufactured from CoCrMo. In addition to the standard insert design, a "deep dish" design is available for patients that may need more stability than the standard design. The "deep dish" insert has a slightly smaller range of motion to provide more restraint than the standard insert design. The gliding surfaces (inserts) and patellas are manufactured from UHMWPE.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses" were completed. Biomechanical testing results demonstrate that the Columbus (CR) Total Knee System is substantially equivalent to other knee systems currently on the market.

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the Columbus Total Knee System is substantially equivalent to:

- Search Evolution Total Knee System (K021313)
- Scorpio Posterior Cruciate Retaining Knee System (K974556)
- Gem Knee System (K994214)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

Ms. Joyce Kilroy
Director of Regulatory Affairs/ Quality Assurance
Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K023788
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: Class II
Product Code: JWH
Dated: November 10, 2002
Received: November 13, 2002

Dear Ms. Kilroy:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023788

Device Name: Columbus (CR) Total Knee System

Indication for Use:

The Columbus (CR) Total Knee System is intended 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 persists, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.

The Columbus Knee is designed for use with bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023788

Prescription Use _____ or Over-the-Counter Use _____

(per 21 CFR 801.109)