K071220 (1/2)

JUN - 1 2007

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

Columbus Total Knee System AS
2 May 2007

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

CONTACT: Matthew M. Hull
800-258-1946 (phone)
610-791-6882 (fax)
matt.hull@aesculap.com (email)

TRADE NAME: Columbus Total Knee System AS

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 Total Knee System Alternate Surface (AS) is substantially equivalent to Aesculap's Columbus Total Knee System PS (K030367), CR (K022672), Smith & Nephew's Genesis II Zirconium "Oxinium" knee (K962557), and Endotec's (B-P) New Jersey Total knee (K012702).

DEVICE DESCRIPTION

The Columbus Total Knee System AS includes both CR and PS variants of the femoral and tibial components for cemented use with the previously cleared UHMWPE Columbus tibial inserts. The Zirconium Nitrate ZrN coating is the only change to the previously cleared Columbus Total Knee System. The coated components are still made from Cobalt Chrome alloy (CoCrMo).

INDICATIONS FOR USE

The Columbus 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.

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TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The base material used for the new Aseculap implants is the same as that used to manufacture the predicate Aesculap devices. The only difference is the addition of a Zirconium Nitrate (ZrN) coating to the CoCrMo implants. The PVD coating method is commonly used on other medical devices as well including the other predicate implants.

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All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap Implant Systems, Inc.
% Mr. Matthew M. Hull
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

JUN - 1 2007

Re: K071220
Trade/Device Name: Columbus Total Knee Systems AS
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prothesis
Regulatory Class: II
Product Code: JWH
Dated: May 2, 2007
Received: May 10, 2007

Dear Mr. Hull:

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 on 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: K071220

Device Name: Columbus Total Knee System AS

Indications for Use:

The Columbus 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.

Mark N Milhous

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

510(k) Number K071220

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)