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K032108

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

SEARCH EVOLUTION (LC) TOTAL KNEE SYSTEM

July 7, 2003

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: Search Evolution (LC) Total Knee System (Porous Coated)

COMMON NAME: Porous Coated Femoral Component

DEVICE CLASS: CLASS II

PRODUCT CODE: MBH

CLASSIFICATION: 888.3565

REVIEW PANEL: Orthopedics

INTENDED USE

The Search Evolution (LC) Total Knee System is intended to replace a knee joint in order to relieve pain and restore knee function, for indications such as, osteoarthritis, inflammatory arthritis, traumatic arthritis, varus, valgus or flexion deformities and revision surgery.
The Search Evolution tibial tray and non-porous coated femoral component are designed for use with bone cement.

The Search Evolution porous coated femoral component is designed for use without bone cement

DEVICE DESCRIPTION

The Search Evolution (LC) Total Knee System is available with two femoral designs. Each retains the PCL, ligament cruciate (LC) during implantation and both femoral components are manufactured from CoCrMo. One is non-porous coated and is intended to be used with bone cement. The other is porous coated and intended to be used without bone cement. The coating is Ti, which conforms to ISO 5832 and is applied using the plasma spray technique.

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All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses" were done where applicable. In addition, testing per "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement" were completed.

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SUBSTANTIAL EQUIVALENCE

Aesculap believes that the new porous coated femoral component of the Search Evolution Total Knee System is substantially equivalent in design to:

- Columbus (CR) Total Knee System (K022672)
- Search Evolution Total Knee System (K021313)
- Scorpio Posterior Cruciate Retaining Knee System (K974556)
- Gem Knee System (K994214)

Substantial equivalence to the intended use of uncemented fixation for the porous coated femoral component is established by:

- 21 CFR 888.3565; Product Code: MBH
- Guidance document: "Class II Special Controls Guidance Document: Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coasted 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

JAN 15 2004

Ms. Joyce Kilroy
Director Regulatory Affairs
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Re: K032108
Trade/Device Name: Search Evolution (LC) Total Knee System (Porous Coated)
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH
Dated: October 16, 2003
Received: October 17, 2003

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. 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/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

510(k) Number (if known): K032108

Device Name: Search Evolution (LC) Total Knee System (Porous Coated)

Indications For Use:

The Search Evolution (LC) Total Knee System is intended to replace a knee joint in order to relieve pain and restore knee function, for indications such as, osteoarthritis, inflammatory arthritis, traumatic arthritis, varus, valgus or flexion deformities and revision surgery.

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The Search Evolution porous coated femoral component is designed for use without bone cement.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhem

...rative
...Neurological Devices

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