AUG 2 1 2007

K070981

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

SEARCH EVOLUTION (LC) TOTAL KNEE SYSTEM
August 20, 2007

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

CONTACT: Lisa M. Boyle
800-258-1946 (phone)
610-791-6882 (fax)

TRADE NAME: Search Evolution (LC) Total Knee System (Plasmapore®)
COMMON NAME: Titanium (Ti.) Plasma Spray Coated Femoral Component
DEVICE CLASS: CLASS II
PRODUCT CODE: JWH
CLASSIFICATION: 888.3560
REVIEW PANEL: Orthopedics

SUBSTANTIAL EQUIVALENCE
Aesculap believes that the titanium plasma spray coated femoral component of the Search Evolution Total Knee System is substantially equivalent in design fundamental technology, and coating when compared to:

- Aesculap Search Evolution Porous Coated Femoral Component (K032108)
- Aesculap Bicontact Hip System (K040191)
- Aesculap Excia Total Hip System (K042344)
- Aesculap Search Evolution Total Knee System (K021313)

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. The titanium plasma spray coated femoral components are intended to be used with bone cement (previously cleared in K021313). It conforms to ISO 5832 and is applied using the plasma spray technique.

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 non-porous titanium plasma spray coated femoral components are designed for use with bone cement.

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All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable.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

TECHNOLOGICAL CHARACTERISTICS (compared to Predicate (s))

The Aesculap titanium plasma spray coated femoral components are considered substantially equivalent to other legally marketed systems with a titanium plasma spray coating. Testing done on the plasma spray coating found it to be similar in performance to previously cleared devices with the same type of coating.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 1 2007

Aesculap Implant Systems, Inc.
% Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K070981
Trade/Device Name: Search Evolution (LC) Total Knee system (Plasmapore®)
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: July 19, 2007
Received: July 23, 2007

Dear Ms. Boyle:

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.

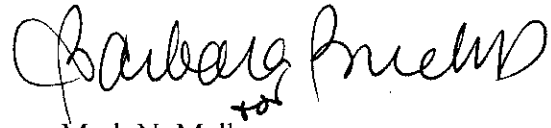
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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 (if known): K070981

Device Name: Search Evolution (LC) Total Knee System

Indication 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.

The Search Evolution non-porous titanium plasma spray coated femoral components are designed for use with bone cement.

Prescription Use X 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)

Barbara Brennan for NXM

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

510(k) Number K070981