SEP 2 2 2008

K081293

3. 510(k) SUMMARY (as required by 21 CFR 807.92)

UNIVATION® Unicompartmental Knee System
May 6, 2008

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

CONTACT: Lisa M. Boyle
610-984-9274 (phone)
610-791-6882 (fax)

TRADE NAME: UNIVATION®

COMMON NAME: Unicompartmental Knee System

CLASSIFICATION NAME: Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/Polymer

REGULATION NUMBER: 888.3530

PRODUCT CODE: HRY

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems®, Inc. believes that the UNIVATION® Unicompartmental Knee System is substantially equivalent to:

- Millar/Galante Precoated Unicompartmental Knee (K880155/K942263/K010685)
- Columbus Total Knee System MIOS CR/PS Tibial Tray (K071499)
- Columbus Total Knee System AS (K071220)

DEVICE DESCRIPTION

The Univation® Unicompartmental Knee System is a prosthesis that replaces only one compartment of the knee condyle which consists of a femoral, tibial and meniscal components that are available in a wide range of sizes. The Univation® Unicompartmental Knee System components are medial unicondylar knee replacements for either the right or left knee. The femoral and tibial components are manufactured from CoCrMo, the meniscal components are manufactured from UHMWPE. The femoral and tibial components are available with either a PMMA (polymethylmethacrylate) or ZrN (zirconium nitride) coating. All components are sterile and for single use only.

INDICATIONS FOR USE

The UNIVATION® Unicompartmental Knee System is indicated for cemented use only in patients undergoing surgery for a severely painful and/or disabled joint damaged as a result of osteoarthritis, traumatic arthritis, or a failed previous implant when only one condyle of the knee (medial) is affected.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap Implant Systems® UNIVATION® Unicompartmental Knee System are offered in a similar range of shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems 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All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable.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 for the Preparation of Premarket Notifications (510(k)s) for Cemented, Semi-Constrained Total Knee Prostheses",
- "Guidance Document for Polymethylmethacrylate (PMMA) Bone Cement', and
- "Class II Special Controls Guidance Document for Knee Joint Patellofemorotibial & Femorotibial Metal/Polyer Porous-Coated 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

SEP 2 2 2008

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

Re: K081293
Trade/Device Name: UNIVATION® Unicompartmental Knee System
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: HRY
Dated: August 7, 2008
Received: August 8, 2008

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 (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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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: K081293

Device Name: UNIVATION® Unicompartmental Knee System

Indications for Use:

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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)

Mark N Milhous

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

510(k) Number K081293