K131167

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

UNIVATION® Unicompartmental Knee System
October 08, 2013

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

CONTACT: Julie Tom Wing
610-984-9147 (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

CLASSIFICATION: Class II

PRODUCT CODE: HRY

OCT 17 2013

PANEL: Orthopedic

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems®, LLC. UNIVATION® Unicompartmental Knee System is substantially equivalent to the original UNIVATION® Unicompartmental Knee System cleared in 510(K) K081293. The indications for use are equivalent to the predicate.

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.

K131167

INDICATIONS FOR USE

The indications for use remain unchanged as follows:

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 entire UNIVATION® Unicompartmental Knee System was cleared under 510(K) K081293. The fundamental scientific technology and materials for UNIVATION® Unicompartmental Knee System remain the same. The indications for use are equivalent to the predicate.

The only differences are a design modification of the femur and tibia at posterior fin and distal teeth.

PERFORMANCE DATA

Aesculap conducted a risk analysis of the design modifications and as a result of the risk assessment, customized endurance testing based upon ISO 14879-1:2000 and ASTM F1800-07 were used to evaluate bone interface geometry of both modified femur and tibia components for 5 million load cycles and 10 million load cycles, respectively. The results were found to be similar to the legally marketed UNIVATION® Unicompartmental Knee System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

Aesculap Implant Systems, LLC
Ms. Julie Tom Wing
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K131167
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: Class II
Product Code: HRY
Dated: September 18, 2013
Received: September 20, 2013

Dear Ms. Tom Wing:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours.

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K131167

Device Name: UNIVATION® Unicompartmental Knee System

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.

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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices