K102424 (pg 1/2)

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

DEC - 9 2010

Prevision Hip System with Recon Ring
December 3, 2010

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

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
Kathy.racosky@aesculap.com

TRADE NAME: Prevision Hip System

COMMON NAME: Femoral Hip Prosthesis

CLASSIFICATION NAME: Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate
Prosthesis, Hip, Semi-constrained, Metal/Polymer, Cemented
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented
Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented

REGULATION NUMBER: 888.3353, 888.3350, 888.3360, 888.3353, 888.3390,

PRODUCT CODE: MEH, JDI, LWJ, LZO, KWY

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the Prevision Hip System with Recon Ring is substantially equivalent to:

- Zimmer, Inc. ZMR Hip System (K992667 & K994286)
- Intermedics Orthopedics Inc., Burch/Schneider Reinforcement Cage (K960678)
- Aesculap Implant Systems Metha Hip System (K071916)
- Aesculap Implant Systems Bicontact (K040191)

DEVICE DESCRIPTION

The Prevision Hip System is a modular system which consists of a proximal body, distal stem and a tension nut. The three individual components utilize a modular junction. The individual components may be assembled by the surgeon in the operating room or in situ to allow independent sizing of the proximal body and distal stem. All proximal components are able to mate with all distal components providing a comprehensive range of combinations offering optimal flexibility. It is designed for use with currently available Aesculap Implant Systems femoral heads, acetabular components and Bipolar cups.

The Prevision Hip System is manufactured from Titanium Alloy and intended for cementless use. The proximal body is plasma sprayed (Plasmapore®) with a secondary coating of Calcium Phosphate (μ-CaP®).

The Recon Ring will be offered in three sizes with left and right configurations. The Recon Ring is manufactured from Titanium. It is designed to be used with the PE acetabular cup cleared in BiContact (K040191).

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the Aesculap Implant Systems Prevision Hip System with Recon Ring.

INDICATIONS FOR USE

The Prevision Hip System is intended for cementless revision hip arthroplasty in patients whose bone stock is of poor quality or inadequate for other reconstruction techniques as indicated by deficiencies of the femoral head, neck, or portions of the proximal femur. The Prevision Hip System is intended for revision only.

The Recon Ring is intended to bridge the areas of acetabular bone loss in patients with acetabular bone deficiency. In addition, the Recon Ring is intended to provide support for an all polyethylene acetabular implant in a cemented application.

Diagnostic indications for use of this device include acetabular dysplasia, osteoporosis, protrusion acetabuli, cystic acetabular roof, reconstruction in cases of defects after fracture, acetabular loosening, tumors or revision surgery.

The general indications associated with the use of the Recon Ring in total hip arthroplasty include:

- Advanced joint destruction resulting from degenerative, posttraumatic or rheumatoid arthritis,
- Fracture or avascular necrosis of the femoral head,
- Failed previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemi-arthroplasty and total hip replacement.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap Implant Systems Prevision Hip System with Recon Ring 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

Testing of the Aesculap Implant Systems Prevision Hip System was performed in accordance with ISO 7206 and ASTM F 2068 and the results were found to be similar to other legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Aesculap Implant Systems LLC
% Ms. Kathy A. Racosky
3773 Corporate Parkway
Center Valley, PA 18034

DEC - 9 2010

Re: K102424
Trade/Device Name: Prevision Hip System with Recon Ring
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: MEH, JDI, LWJ, LZO, KWY
Dated: December 3, 2010
Received: December 6, 2010

Dear Ms. Racosky:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

DEC - 9 2010

510(k) Number: K102424 (pg 1/1)

Device Name: Prevision Hip System with Recon Ring

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)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102424