

B. 510(k) SUMMARY (as required by 21 CFR 807.92) K081973 (pg 1/2)**Consensus Acetabular Cups in Aesculap Hip Systems**
8 July 2008

AUG - 7 2008

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

CONTACT: Matthew M. Hull
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TRADE NAME: Excia and Metha Hip Systems (Consensus Acetabular Cup)

COMMON NAME: Total Hip System

CLASSIFICATION NAME: Prosthesis, hip, semi-constrained, metal/ceramic/polymer,
cemented or non-porous uncemented prosthesis

Prosthesis, hip, semi-constrained, metal/polymer, porous
uncemented

REGULATION NUMBER: 888.3353/ 888.3358

PRODUCT CODE: LZO/ LPH

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Consensus Acetabular Cup is a line extension of Aesculap's Excia (K042344 – K062684) and Metha (K071916 & K080584) Hip Systems that were previously cleared for use with acetabular cups. The Consensus Acetabular Cup components have been cleared in K020153 – K070061 for use with the Consensus and Unisyn hip systems from Hayes Medical.

DEVICE DESCRIPTION

The Consensus Acetabular Cup from Hayes Medical is a Titanium alloy shell with a highly cross linked polyethylene insert. The Consensus acetabular cups are available in 28mm, 32mm, and 36mm ID's, a variety of sizes, and in either standard or hooded versions. The shells are available with or without screws. The Aesculap Excia hip systems also comes in 28mm – 36 mm ID's, it is available in both cemented and uncemented variants, and a wide range of sizes. Aesculap's Metha hip system also comes in 28 – 36 mm ID's but is for uncemented use, and also comes in a variety of sizes. The PlasmaCup acetabular cup from Aesculap is cleared for use with both the Excia and Metha systems.

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INDICATIONS FOR USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Indications for use of the CONSENSUS® HIP SYSTEM-PRIMARY HIP:

- A) Significantly impaired joints resulting from rheumatoid, osteo, and posttraumatic arthritis.
- B) Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C) Proximal femoral fractures.
- D) Avascular necrosis of the femoral head.
- E) Non-union of proximal femoral neck fractures.
- F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Acetabular components are indicated for cemented and cementless use.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

There are no changes to the Hayes Consensus acetabular cup nor to the Aesculap Excia and Metha hip systems. The inner dimensions of the Aesculap PlasmaCup acetabular cup inserts are identical to those of the Hayes Consensus acetabular cups. The difference is that the Consensus inserts are highly crosslinked polyethylene (UHMWPE) and the Aesculap PlasmaCup inserts are regular polyethylene (UHMWPE).

PERFORMANCE DATA

Based upon the engineering evaluation of the dimensions of these components no additional performance data was required.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap Implant Systems, Inc.
% Mr. Matthew M. Hull, RAC
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

AUG - 7 2008

Re: K081973
Trade/Device Name: Consensus Acetabular Cups for use with the Aesculap Excia and Metha Hip Systems
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: LZO, LPH
Dated: July 9, 2008
Received: July 10, 2008

Dear Mr. Hull:

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 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: K081973 (pg 1/1)

Device Name: Consensus Acetabular Cups for use with the Aesculap Excia and Metha Hip Systems

Indications for Use:

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Indications for use of the CONSENSUS® HIP SYSTEM-PRIMARY HIP:

- A) Significantly impaired joints resulting from rheumatoid, osteo, and posttraumatic arthritis.
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- F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Acetabular components are indicated for cemented and cementless use.

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)

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

510(k) Number K081973 002