K021878

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Summary of Safety and Effectiveness
for
ESKA Modular Hip System Acetabular Components

This safety and effectiveness summary for the ESKA Modular Hip System Acetabular Components is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

MAR 0 4 2003

1. Submitter :
ESKA Implants GmbH & Co.
Grapengießerstraße 34
D-23556 Lübeck, Germany
(49) 451 89000-0

Contact Person :
Thomas P. Monkus
ESKA America Corporation
101 Riverfront Blvd., Suite 600
Bradenton, FL 34205
Telephone: (941) 744-5400

Date Prepared: February 25, 2003

2. Tradename : ESKA Modular Hip System Acetabular Components
Common Name : Total Hip System
Classification Name : Hip joint metal /polymer/ metal semi-constrained porous uncemented prosthesis (888.3358)

3. Predicate or legally marketed devices which are substantially equivalent :

- PFC Total Hip System (Johnson & Johnson)
- ESKA Modular Hip System (ESKA America)
- Vitalock Acetabular System (Howmedica Stryker Osteonics)
- PCA Cluster Acetabular System (Howmedica Stryker Osteonics)

4. Description of the device :

The ESKA Modular Hip System Acetabular Components are modular acetabular components used in conjunction with the company's femoral stems, for the replacement of severely disabled hip joints. The system consists of porous acetabular shells, modular femoral heads, and modular acetabular liners. The acetabular components are porous coated hemispherical shells with modular UHMWPE inserts.

Materials: The devices are manufactured from CoCrMo alloy, Ultra High Molecular Weight Polyethylene (UHMWPE), per ASTM and ISO standards.

Function: The system functions to provide pain relief and improved function to the hip that has been disabled from arthritic conditions or trauma.

5. Intended Use :

The ESKA Modular Total Hip System Acetabular Components are indicated for uncemented use in the treatment of severely disabled hip joints resulting from painful osteo-, rheumatoid, and posttraumatic arthritis, and the late stages of avascular necrosis, and for revision of previous hip surgeries.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the ESKA Modular Hip System Acetabular Components and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

ESKA Implants GmbH & Co.
c/o Mr. Thomas P. Monkus, RAC
Director, Regulatory Affairs and Business Development
ESKA America Corporation
101 Riverfront Boulevard, Suite 600
Bradenton, Florida 34205

Re: K021878
Trade/Device Name: ESKA Modular Hip System Acetabular Components
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: December 2, 2002
Received: December 4, 2002

Dear Mr. Monkus:

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.

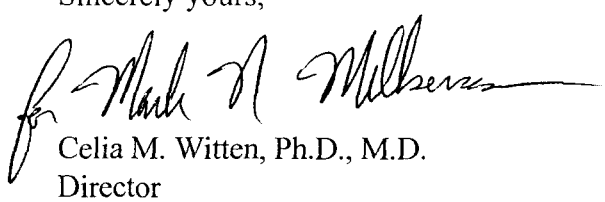
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4659. 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021878

510(k) Number : K021878

Device Name : ESKA Modular Total Hip System Acetabular Components

Indications For Use :

The ESKA Modular Total Hip System Acetabular Components are indicated for uncemented use in the treatment of severely disabled hip joints resulting from painful osteo-, rheumatoid, and post-traumatic arthritis, and the late stages of avascular necrosis, and for revision of previous hip surgeries.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ____ OR Over-the-counter use _____
(PER 21 CFR 801.109)

(optional format 1-2-96)

for Mark N Milhous

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

510(k) Number K021878