SEP 2 2 2003

K030867

Summary of Safety and Effectiveness
for the
ESKA Modular Hip System Cemented

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

1. Submitter :

ESKA Implants GmbH & Co.
Grapengießerstraße 34
D-23556 Lübeck
(0451) 89000-0

Date Prepared: May 20, 2003

Contact Person :

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

2. Trade Name: ESKA Modular Hip System Cemented
Common Name: Total Hip System
Classification Name: Hip joint metal /polymer semi-constrained cemented prosthesis (888.3350)

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

- Omnifit Hip System (Osteonics)
- PFC Cemented Total Hip System (Johnson & Johnson)
- Link SPII Hip System (Link)
- Exactech Cemented Total Hip System (Exactech)

4. Description of the device :

The ESKA Modular Hip System Cemented is a total hip system used for the replacement of severely disabled hip joints. It consists of femoral stems, modular femoral heads and acetabular components. The modular femoral stems are anatomically designed in left and right configurations, with anteverted femoral necks. They are available in varying primary and revision lengths. There are collared and collarless options. Standard and lateralized geometries are offered. The stems feature a grit-blasted surface along their entire length and a 12/14 Morse type taper trunnion.

The modular femoral heads are available in various diameters from 26mm to 32mm, and in varying neck lengths.

The acetabular components are hemispherical all-polyethylene designs in a range of inner and outer diameters, with various offset options. The outer diameters incorporate radial and circumferential cement retention grooves and a titanium radiographic marker wire.

Materials: The devices are manufactured from CoCrMo alloy and 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 Hip System Cemented is indicated for cemented 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 the 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 Cemented 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

SEP 2 2 2003

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

Re: K030867
Trade/Device Name: ESKA Modular Hip System Cemented
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: August 20, 2003
Received: August 21, 2003

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,

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

Enclosure

510(k) Number (if known) : K030867

Device Name : ESKA Modular Hip System Cemented

Indications For Use :

The ESKA Modular Hip System Cemented is indicated for cemented 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 ____
(PER 21 CFR 801.109)

OR

Over-the-counter use _____
(optional format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 03 0867