

K993027

APR 6 2000

Summary of Safety and Effectiveness
for
ESKA Modular Hip System

This safety and effectiveness summary for the ESKA Modular Hip System 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, Germany
(0) 451- 89000-0

Contact Person :

Thomas P. Monkus, RAC
635 South Orange Avenue
Sarasota, FL 34236
Telephone: (941) 362-4877

Date Prepared: August 31, 1999

2. Tradename :

ESKA Modular Hip System

Common Name : Total Hip System

Classification Name : Hip joint metal /polymer /metal semi-constrained porous coated uncemented prosthesis (888.3358)

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

- Omnifit Hip System (Osteonics)
- Horizon Hip System (BioPro)
- Sentry Hip System and E-Series Hip System (Howmedica)
- AML Hip System (DePuy)
- VitaLock, OsteoLock and PCA Acetabular Cup Systems (Howmedica)
- Ranawat / Burstein Total Hip System (Biomet)
- Omega Total Hip System (OsteoImplant Technology)
- Hedrocel Acetabular Cup System (Implex)

4. Description of the device :

The ESKA Modular Hip System is a total hip system used for the replacement of severely disabled hip joints. It consists of femoral stems and heads, acetabular shells and modular liners, bipolar femoral heads, and bone screws. The femoral stems are anatomically designed in left and right configurations, with anteverted femoral necks. There are fully porous, proximally porous, collared and collarless options. The acetabular components are porous, with various liner options and screws for supplementary fixation. Pre-assembled bipolar and unipolar components are also available.

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 is indicated for 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 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 6 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas P. Monkus, RAC
Director, Regulatory & Quality Systems
SPECS USA, Inc.
635 South Orange Avenue
Sarasota, Florida 34236

Re: K993027
Trade Name: ESKA Modular Hip System
Regulatory Class: II
Product Code: LPH/JDI
Dated: January 12, 2000
Received: January 14, 2000

Dear Mr. Monkus:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

Page 2 - Mr. Thomas P. Monkus, RAC

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K993027

Device Name: ESKA Modular Hip System

Indications For Use:

The ESKA Modular Hip System is indicated for use in the treatment of rheumatoid arthritis osteoarthritis, post-traumatic arthritis, avascular necrosis, non-union of femoral neck fractures, fracture dislocation of the hip, conversion of unsuccessful arthrodeses and 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)

Dan R. Wadner

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K993027

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)