

510(k) Summary

Proprietary Name: Kerboull Cross

Common Name: Acetabular Reinforcement Shell

Classification Name and Reference: Prosthesis, Hip, Acetabular Mesh
21 CFR 878.3300

NOV - 3 1997

Proposed Regulatory Class: Class II

Device Product Code: OR(79) JDJ

For information contact:

Frank Maas
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7875
Fax: (201) 507-6870
Date Summary Prepared: 8-8-97

The Kerboull Cross is intended to be used to reconstruct the acetabulum in primary and/or revision total hip arthroplasty. Specifically, this device is used to reinforce the medial wall of the acetabulum to achieve stable fixation of the acetabular component in the presence of a deficient or weakened medial wall caused by severe inflammatory disease, fracture of the medial wall, or failed total hip arthroplasty.

This device will be manufactured in three materials; Stainless Steel, Vitallium, and Titanium alloy.

The Kerboull Cross is a hemi-spherical, metal shell that incorporates several flanges and screw holes and is shaped to fit into the acetabulum. These devices are available in a range of outer diameters to fit varying anatomical requirements.

The substantial equivalence of the Kerboull Cross is based on an equivalence in intended use, materials, design, and relative indications and contraindications to Depuy's Protrusio Cage (K962007).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1997

Mr. Frank Maas
Manager, Regulatory Affairs
Howmedica Incorporated
Pfizer Medical Technology Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K972928
Kerboulli Cross Acetabular Reinforcement Shell
Regulatory Class: II
Product Code: JDI
Dated: August 8, 1997
Received: August 8, 1997

Dear Mr. Maas:

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 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.

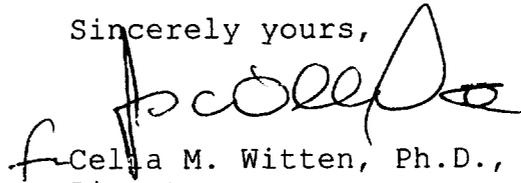
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Frank Maas

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.

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K972928

Device Name: Kerboull Cross

Indications for Use:

The Kerboull Cross is intended to be used to reconstruct the acetabulum in primary and/or revision total hip arthroplasty. Specifically, this device is used to reinforce the medial wall of the acetabulum to achieve stable fixation of the acetabular component in the presence of a deficient or weakened medial wall caused by severe inflammatory disease, fracture of the medial wall, or failed total hip arthroplasty.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

[Signature] (Optional Format 1-2-96)

(Division Sign-Off)
Division of **General Restorative Devices**
510(k) Number K972928