

K971705

AUG - 6 1997

**510(k) SUMMARY - IMPLEX HEP ACETABULAR
CUP SYSTEM, CEMENTED**

Submitter Name: Implex Corp.

Submitter Address: 80 Commerce Drive
Allendale, New Jersey 07401-1600

Contact Person: Robert Cohen or Robert Poggie

Phone Number: (201) 818-1800

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Date Prepared: July 28, 1997

Device Trade Name: Implex HEP Acetabular Cup System, Cemented

Device Common Name: Acetabular Cup

Classification Name: Prosthesis, Hip, Acetabular Component, Cemented

Predicate Device(s): Implex A-230 Porous Acetabular Cup System, Cemented;
Implex Hydrocel® Acetabular Restrictor

Device Description: Implex HEP Acetabular Cups, Cemented, are available in OD sizes from 40 mm to 70 mm (in 2 mm increments), and with four possible ID size options (22 mm, 26 mm, 28 mm, and 32 mm). Implex HEP Acetabular Cups are to be implanted using the Implex Acetabular Cup Instrumentation System.

Indications for Use: The use of the Implex HEP Acetabular Cup System, Cemented, is indicated for:

- a) Total Hip Replacement in severely disabled joints as a result of degenerative arthritis or avascular necrosis;
- b) Secondary revision of a previously unsuccessful acetabular component;
- c) Other hip problems where clinical experience has shown that alternative modes of treatment are less likely to achieve satisfactory results;
- d) Fracture dislocation of the hip, or irreducible fractures in which adequate fixation cannot be obtained;
- e) Non-union of femoral neck or head fractures; and
- f) Salvage of a failed primary or secondary total or hemi hip.

510(k) Summary, Continued

Device Technological Characteristics and Comparison to Predicate Device(s):

The surgical instrumentation and design geometry of the predicate Implex A-230 Porous Acetabular Cup System, Cemented, and the Implex HEP acetabular Cup System, Cemented, are equivalent. The primary difference between the two device systems is that the Implex HEP Acetabular Cup, Cemented shell is comprised of Hedrocel®, and the Implex A-230 Porous Acetabular Cup is comprised of porous coated titanium alloy.

The Hedrocel® material used in the Implex HEP Acetabular Cup System, Cemented, is identical to the Hedrocel® material which comprises the Implex Hedrocel® Acetabular Restrictor.

Performance Data:

Testing conducted to characterize the materials and the performance characteristics of the device under defined laboratory conditions was provided to support a finding of substantial equivalence.

Conclusion:

The Implex HEP Acetabular Cup System, Cemented, is substantially equivalent to the identified predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Glenn N. Byrd, MBA
Associate Director of Regulatory Affairs
Advanced Bioresearch Associates
Authorized Regulatory Agent for Implex Corporation
1700 Rockville Pike, Suite 450
Rockville, Maryland 20852-1631

AUG - 6 1997

Re: K971705
Implex HEP Acetabular Cup System, Cemented
Regulatory Class: II
Product Code: JDI
Dated: May 8, 1997
Received: May 8, 1997

Dear Mr. Byrd:

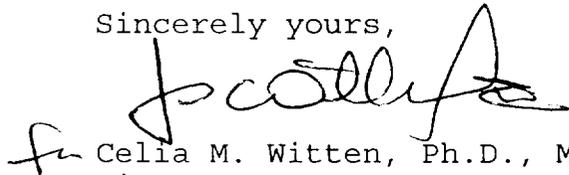
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 pre-market 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.

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,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

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): K971705

Device Name: Implex HEP Acetabular Cup System,
Cemented

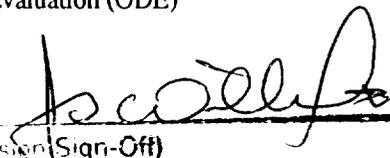
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- e) Non-union of femoral neck or head fractures; and
- f) Salvage of a failed primary or secondary total or hemi hip.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)



 (Sign-Off)
 Director of General Restorative Devices
 510(k) Number K971705

Prescription Use X
(Per 21 CFR 801.109)

OR...

Over-The-Counter Use _____

(Optional Format 1-2-96)