

JUN 19 1997

K964509**510(k) SUMMARY - IMPLEX A-240 HEP ACETABULAR CUP SYSTEM**

**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

**Fax Number:** (201) 818-0567

**Date Prepared:** November 8, 1996

**Device Trade Name:** Implex A-240 HEP Acetabular Cup System

**Device Common Name:** Acetabular Cup

**Classification Name:** Prosthesis, Hip, Acetabular Component, Non-Cemented

**Predicate Device:** Implex A-230 Porous Acetabular Cup System, Non-Cemented

**Device Description:** Implex A-240 HEP Acetabular Cups are available in OD sizes from 40 mm to 72 mm (in 2 mm increments), and with 4 possible ID size options (22 mm, 26 mm, 28 mm, and 32 mm). Implex A-240 HEP Acetabular Cups are to be implanted using the Implex Acetabular Cup Instrumentation System.

**Indications For Use:** The use of the Implex A-240 HEP Acetabular Cup System 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.

**Device Technological  
Characteristics and  
Comparison to  
Predicate Device:**

The surgical instrumentation and design geometry of the predicate Implex A-230 Porous Acetabular Cup System, Non-Cemented, and the Implex A-240 HEP Acetabular Cup System are equivalent. The primary difference between the two device systems, is the porous metal of the shell. The Implex A-240 HEP Acetabular Cup shell is comprised of porous tantalum, and the Implex A-230 Porous Acetabular Cup is comprised of porous coated titanium alloy.

**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 A-240 HEP Acetabular Cup System is substantially equivalent to the predicate device in terms of intended use, safety, and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

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Re: K964509  
Trade Name: Implex A-240 HEP  
Acetabular Cup System  
Regulatory Class: II  
Product Code: LPH  
Dated: March 21, 1997  
Received: March 21, 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.

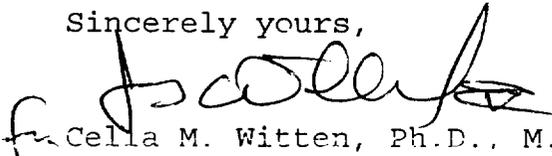
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic

GMP 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.

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

