APR 1 4 1998

K980486

510(k) SUMMARY - IMPLEX HEP Acetabular Cup Revision System, Cemented or Cementless

Submitter Name:	Implex Corp.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person(s):	Robert Poggie or Robert Cohen
Phone Number:	(201) 818-1800
Fax Number:	(201) 818-0567
Date Prepared:	February 6, 1998
Device Trade Name:	Implex HEP Acetabular Revision Cup, Cemented or Cementless
Device Common Name:	Acetabular Cup
Classification Name:	Prosthesis, Hip, Acetabular Component, Cemented, Cementless
Predicate Devices:	Implex HEP Porous Acetabular Cup System, Cemented and Cementless; Implex Porous Elliptical Revision Cup System, Cemented and Cementless, Implex Acetabular Cup Screw System.
Device Description:	Implex HEP Acetabular Revision Cups, Cemented or Cementless, 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 HEP Revision Acetabular Cups are to be implanted using the Implex Acetabular Cup Instrumentation System.
Intended Use:	For use where severe degeneration, trauma, or other pathology of the hip joint indicates cemented, cementless, or hybrid total hip arthroplasty. This device is intended for either cementless or cemented use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1998

Robert A. Poggie, Ph.D.
Director of Applied Research
Implex Corporation
80 commerce Drive
Allendale, New Jersey 07401-1600

Re: K980486
Trade Name: Implex HEP Acetabular Revision Cup
Regulatory Class: II
Product Codes: JDI and LPH
Dated: February 6, 1998
Received: February 9, 1998

Dear Dr. Poggie:

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.

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,

Stephen Rhodes

for 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): K980486

Device Name: Implex HEP Acetabular Revision Cup

Indications For Use:

Intended for use in the acetabulum where severe degeneration, trauma, or other pathology of the hip joint indicates cemented, cementless, or hybrid 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 (Per 21 CFR 801.109) Yes OR... Over-The-Counter Use No

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980486

(Optional Format 1-2-96)