DEC - 3 1998

K983128

510(k) SUMMARY
IMPLEX Hedrocel® Replacement Cup Insert, Cemented

Submitter Name:	Implex Corp.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person:	Robert Poggie, PhD or John Schalago, RAC
Phone Number:	(201) 818-1800
Fax Number:	(201) 818-0567
Date Prepared:	September 3, 1998
Device Trade Name:	Implex Hedrocel® Replacement Cup Insert
Device Common Name:	Acetabular Cup
Classification Name:	Prosthesis, Hip, Acetabular Component, Cemented
Predicate Devices:	Implex Hedrocel® Porous Acetabular Cup System, Implex Replacement Acetabular Cup Insert System, Osteonics GAP II Restoration Acetabular shell with Omnifit® Polyethylene Insert Bearing.
Device Description:	The Implex Hedrocel® Replacement Cup Inserts, cemented, are compatible with the family of Hedrocel® acetabular cups in OD sizes from 40 to 70 mm. The replacement inserts are available with four ID size options (22 mm, 26 mm, 28 mm and 32 mm) and in 0°, 10°, and 20° face angles.
Intended Use:	The Implex Hedrocel® Replacement Cup Insert, cemented, is intended for use as a *in-situ* replacement polyethylene bearing surface under circumstances of joint instability, wear and/or damage caused by the patient during use.
Device Technological Characteristics and Comparison to Predicate Device:	A comparison of the principal device technological characteristics to the predicate devices demonstrates that the bearing surface is substantially equivalent to commercially available polyethylene bearing surfaces.

Performance Data: Testing conducted to evaluate the fatigue characteristics of the device under defined laboratory conditions was provided to support a finding of substantial equivalence.

Conclusion: The Implex Hedrocel® Replacement Cup Insert is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 1998

John A. Schalago, RAC
Regulatory Affairs Manager
Implex Corporation
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K983128
Trade Name: Implex Hedrocel® Replacement Cup Insert
Regulatory Class: II
Product Code: JDI
Dated: September 4, 1998
Received: September 8, 1998

Dear Mr. Schalago:

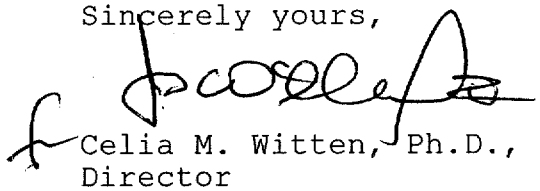
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K983128

Device Name: Implex Hedrocel® Replacement Cup Insert

Indications For Use:

The Implex Hedrocel® Replacement Cup Insert, cemented, is intended for use as an *in-situ* replacement polyethylene bearing surface under circumstances of joint instability, wear and/or damage caused by the patient during use.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983128