JUL 31 1998

K982302

510(k) SUMMARY - IMPLEX CKS Hedrocel® Tibial Spacers

Submitter Name:	Implex Corp.
Submitter Address:	80 Commerce Drive Allendale, New Jersey 07401-1600
Contact Person(s):	John Schalago, RAC or Robert Poggie, Ph.D.
Phone Number:	(201) 818-1800
Fax Number:	(201) 818-0567
Date Prepared:	June 30, 1998
Device Trade Name:	Implex Continuum Knee System Hedrocel® Tibial Spacers
Device Common Name:	Tibial Spacers
Classification Name:	Prosthesis, Knee, Spacers, Cemented
Substantial Equivalence:	**The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.**
Predicate Devices:	The Implex CKS Revision Tibial Spacers, the Implex Hedrocel® Revision Femoral Spacers, the Johnson & Johnson PFC Modular Knee System, and the Zimmer IB II Modular Knee System
Device Description:	The CKS Hedrocel® Tibial Spacers will have four thickness options of 3, 6, 9, and 12 mm and is offered in full and half shapes. The Hedrocel® Tibial Spacers are also offered in wedge configurations, 5 to 25 degrees in 5 degree increments, in full, half and quarter wedge shapes. The CKS Hedrocel® Tibial Spacers are comprised of Hedrocel® porous tantalum and are fastened to Implex Continuum Knee System Revision Tibial Components with titanium alloy spacer bolts.

Intended Use:

The Implex Continuum Knee Hedrocel® Tibial Spacers are indicated for use in the reconstruction of bony defects in knee reconstruction due to severe degeneration, trauma, or other pathology of the knee joint, and in the revision or salvage of failed, previously reconstructed knee procedures and implants. This device is intended for cemented use only.

Performance Data:

Previous testing of the Hedrocel® porous tantalum demonstrates that Hedrocel® should function as intended. The relevant data is found in MAF #920.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1998

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

Re: K982302
Implex Continuum Knee System: Hedrocel® Tibial Spacers
Regulatory Class: II
Product Code: JWH
Dated: June 30, 1998
Received: July 1, 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

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): K982302

Device Name: Implex Continuum Knee - Hedrocel® Tibial Spacers

Indications For Use:

The Implex Continuum Knee Hedrocel Tibial Spacers are indicated for use in the reconstruction of bony defects in knee reconstruction due to severe degeneration, trauma, or other pathology of the knee joint, and in the revision or salvage of failed, previously reconstructed knee procedures and implants. This device is intended for cemented use only.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982302

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

(Optional Format 1-2-96)