

3/15/99

K98 3835

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

REVISION HEDROCEL® PATELLA

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) 818-1600

Fax Number: (201) 818-0567

Date Prepared: October 29, 1998

Device Trade Name: Continuum Patella-Revision Hedrocel®

Device Common Name: Prosthesis, Patellar

Classification Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis

Predicate Device(s): Patellar Component of Continuum Knee System (CKS), Implex Corp. (K882322); Continuum Porous Patella, Implex Corp. (K971879), Konstruct Patellar, Biomet, Inc. (K960856)

Device Description: The Revision Hedrocel® Patella is a modular porous backed patella consisting of a Hedrocel® Patellar Backing with titanium alloy suture ring and the current commercially available Continuum® Patella. The Revision Hedrocel® Patella provides the surgeon a method for augmenting defects in the patella typically encountered during revision surgery of the knee.

Intended Use: The Implex Revision Hedrocel® Patella is intended as the patellar component of the Continuum Knee System whose indications for use include: 1) noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis, 2) rheumatoid arthritis, 3) correction of functional deformity, 4) revision procedures where other treatments or devices have failed, 5) treatment of fractures that are unmanageable using other techniques, and 6) complications from a failed prosthesis.

510(k) Summary (continued)

**Intended Use
(continued)**

This device is intended for use with bone cement and supplemental fixation by means of suture attachment. Supplemental suture attachment may be used in cases where additional device support can be obtained.

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

The materials, design and articulating surface geometry of the Revision Hydrocel® Patella is similar and/or identical to the claimed predicate devices from Implex Corp. and Biomet Inc.

Performance Data:

Based on similarities in design of the Revision Hydrocel® Patella and the predicate devices, the performance testing submitted in K882322 and K971879, and Hydrocel® materials' data found in MAF #920, supports the conclusion that the device will perform as intended.

Conclusion:

The Revision Hydrocel® Patella is substantially equivalent to the predicate devices 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

MAR 15 1999

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

Re: K983835
Trade Name: Implex Revision Hedrocel® Patella
Regulatory Class: II
Product Code: JWH
Dated: January 21, 1999
Received: January 22, 1999

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.

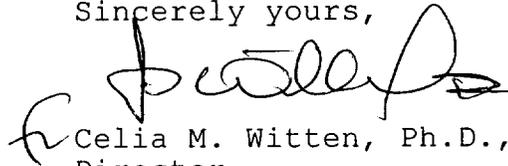
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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.

Page 2 - Robert A. Poggie, Ph.D.

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): K983835

Device Name: Implex Revision Hedrocel® Patella

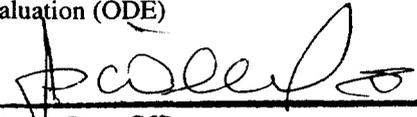
Indications For Use:

The Implex Revision Hedrocel® Patella is intended as the patellar component of the Continuum Knee System whose indications for use include: 1) noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis, 2) rheumatoid arthritis, 3) correction of functional deformity, 4) revision procedures where other treatments or devices have failed, 5) treatment of fractures that are unmanageable using other techniques, and 6) complications from failed prosthesis.

This device is intended for use with bone cement and supplemental fixation by means of suture attachment. Supplemental suture attachment may be used in cases where additional device support can be obtained.

(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 K983835

Prescription Use Yes
(Per 21 CFR 801.109)

OR...

Over-The-Counter Use No

(Optional Format 1-2-96)

(Division Sign-Off)