

K980781

MAY 22 1998


510(k) SUMMARY - IMPLEX CKS Hedrocel® Revision Femoral Spacers

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
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Date Prepared: May 14, 1998
Device Trade Name: Implex Continuum Knee System Hedrocel Revision Femoral Spacers
Device Common Name: Revision Femoral Spacers
Classification Name: Prosthesis, Knee, Femoral 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 Femoral Spacers, the Implex Continuum Porous Patella, and the Implex Hedrocel Acetabular Restrictor.

Device Description: The CKS Hedrocel Distal Femoral Spacers will have 4 thickness options of 4, 8, 12, and 16 mm. The distal femoral spacers will be available in both full and chamfered spacer options. The CKS Hedrocel Posterior Femoral Spacers will be available in 3 thickness options of 4, 8, and 12 mm. The CKS Hedrocel Spacers are comprised of Hedrocel porous tantalum and are to be fastened to Implex Continuum Knee System Revision Femoral Components using the same instrumentation and fastener bolts.

Intended Use: The Implex CKS Hedrocel Revision Femoral Spacers are indicated in the revision or salvage of failed previously reconstructed knee procedures and implants; particularly in situations where bone loss has occurred from removal of prior implantations, infection or trauma. This device is intended for cemented use only.

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Indications For Use:

The use of the Continuum Knee System Hydrocel Revision Femoral Spacers are indicated for:

- a) For cemented use only.
- b) Total Knee Replacement (TKR) in severely disabled joints as a result of degenerative arthritis;
- c) Secondary revision of a previously unsuccessful revision femoral component;
- d) Other knee problems where clinical experience has shown that alternative modes of treatment are less likely to achieve satisfactory results;
- e) Trauma, or other fractures in which adequate bony fixation cannot be obtained;
- f) Non-union of the proximal tibia; and
- g) Salvage of a failed primary or secondary total knee or uni-knee arthroplasty.

Performance Data:

Previous testing of the predicate devices and their respective materials are sufficient for substantial equivalence determination. The relevant data is found in Master File MAF #920 and K962468.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 1998

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

Re: K980781
Trade Name: Implex Continuum Knee System Hedrocel
Revision Femoral Spacers
Regulatory Class: II
Product Code: JWH
Dated: February 27, 1998
Received: March 2, 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.

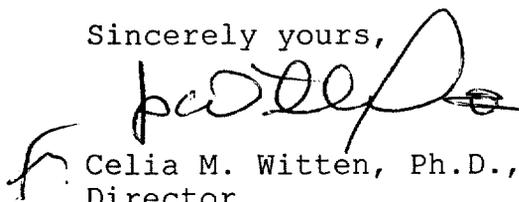
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

