

JUL 24 1997

K971789

**510(k) SUMMARY - CONTINUUM PATELLAR**

**Submitter Name:** Implex Corp. (Implex)

**Submitter Address:** 80 Commerce Drive  
Allendale, New Jersey 07401-1600

**Contact Person:** Robert Cohen  
Vice President, Product Development

**Phone Number:** (201) 818-1600

**Fax Number:** (201) 818-0567

**Date Prepared:** July 22, 1997

**Device Trade Name:** Continuum Patellar

**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); Porous Genesis Patellar,  
Richards Medical Company (K890132); Duracon Inset  
Patella with Central Peg, Howmedica (K961482).

**Device Description:** The Continuum Patellar is fabricated from Hedrocel® and UHMWPE. The UHMWPE is direct compression molded into the Hedrocel®, thereby creating the articulation surface. The Continuum Patellar is intended for use with bone cement when performing total knee arthroplasty or revisions with legally marketed Implex Continuum Femoral and Tibial components.

**Intended Use:** The Continuum Patellar 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, and 5) treatment of fractures that are unmanageable using other techniques. This device is intended for use with bone cement.

**510(k) Summary (continued)**

---

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

The two-part design and articulating surface geometry of the Continuum Patellar is similar and/or identical to the claimed predicate devices from Implex Corp., Richards Medical Company, and Howmedica.

**Performance Data:**

Performance testing of the Continuum Patellar demonstrates its equivalence to the claimed predicate devices.

**Conclusion:**

The Continuum Patellar is substantially equivalent to the predicate devices in terms of intended use, safety, and effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 24 1997

Glenn N. Byrd, MBA  
Associate Director of Regulatory Affairs  
Authorized Regulatory Agent for Implex Corporation  
Advanced Bioresearch Associates  
1700 Rockville Pike, Suite 450  
Rockville, Maryland 20852

Re: K971789  
Implex Continuum Porous Patellar  
Regulatory Class: II  
Product Code: JWH  
Dated: May 14, 1997  
Received: May 14, 1997

Dear Mr. Byrd:

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 limitation:

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.

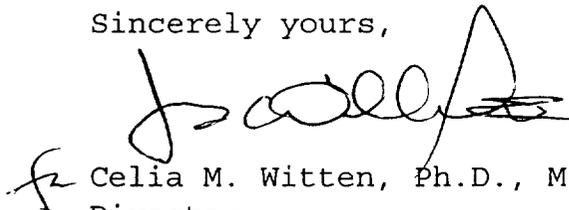
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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 at (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a large, stylized initial "C" and a horizontal line extending to the right.

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): KA71789

Device Name: Implex Continuum Porous Patellar

Indications For Use:

The Implex Continuum Porous Patellar 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, and 5) treatment of fractures that are unmanageable using other techniques. This device is intended for use with bone cement.

(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 KA71789

Prescription Use X  
(Per 21 CFR 801.109)

OR...

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)