510(k) SUMMARY - IMPLEX CK Unity Tibial Component, Cemented

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
Fax Number:	(201) 818-0567
Date Prepared:	October 29, 1998
Device Trade Name:	Implex Continuum Knee Unity Tibial Component, Cemented
Device Common Name:	Tibial Component
Classification Name:	Prosthesis, Knee, Tibial Component, Cemented
Predicate Devices:	The Implex Continuum Knee System, Cemented, the Implex Continuum All-Poly Tibial Component, Cemented, the Continuum Porous Patella, Cemented, and the HEP Acetabular Cup, Cemented, Protek All-Poly Component, Richards Medical Tricon-P and Tricon-M.
Device Description:	The Implex Continuum Knee Unity Tibial Component, Cemented, is available in 8 thickness sizes from 10 mm to 22 mm, in 2 mm increments, and a 26 mm option; and A-P dimensions from 41 mm to 57 mm, and M-L dimensions from 62 mm to 89 mm. The Implex CK Unity Tibial Component is comprised of Hedrocel porous tantalum and UHMWPE. The CK Unity Tibial component is offered in two fixation post options; option A with hexagonal Hedrocel® posts, and option B with polyethylene fixation pegs. The CK Unity Tibial Component is to be implanted using the Implex Continuum Knee System Instrumentation and Surgical Protocol.
Intended Use:	For use where severe degeneration, trauma, or other pathology of the knee joint indicates cemented total knee arthroplasty. This device is intended for cemented use only.
Performance Data:	Previous testing of the predicate devices and associated materials are sufficient for substantial equivalence determination. The relevant data is found in Master File MAF #920 and K964509.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1998

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

Re: K980637
Implex Continuum Knee Unity Tibial Component, Cemented
Regulatory Class: II
Product Code: JWH
Dated: November 3, 1998
Received: November 4, 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). 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. The thinnest tibial component available is the nominal "10mm" sized component, which has a minimum polyethylene thickness under the condyles of 6mm.

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

3. 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.

4. 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): K980637

Device Name: Implex Continuum Knee Unity Tibial Component

Indications For Use:

The Implex Continuum Knee Unity Tibial Component is indicated for use where severe degeneration, trauma, or other pathology of the knee joint indicates cemented total knee arthroplasty.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980637