

JUN - 8 1998

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

Submitter Name: Implex Corp.

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

**Establishment
Registration Number:** 2247737

Contact Person(s): John Schalago, RAC, Regulatory Affairs Department
Robert, Poggie, Ph.D, Applied Science

Phone Number: (201) 818-1800

Fax Number: (201) 818-0567

Date Prepared: April, 1998

Device Trade Name: Implex Continuum Knee System: Porous Tibial Component,
Cemented

Device Common Name: Tibial Component

Classification Name: Prosthesis, Knee, Tibial Component, 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.

Device Description: The CKS: Porous Tibial Tray component is a fixed keel tibial tray with a porous titanium bead coating for fixation. The CKS Porous Coated Tibial Tray is intended for cement use only and is offered in the same range of sizes as the current CKS Tibial Tray component. The tibial base plates have a symmetrical design, providing greater rotational freedom when aligning components

without significantly sacrificing coverage of proximal tibia. Components are machined from forged titanium, which provides excellent fatigue strength, load transfer and biocompatibility.

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: The CK Porous Tibial Tray has demonstrated acceptable performance in mechanical tests that were conducted in accordance with CDRH recognized standards and Design Verification requirements of 21 CFR § 820.30.

Substantial Equivalence Implex Corp believes that the CK Porous Tibial Tray is substantially equivalent to the predicate devices in the table below. This determination of substantial equivalence is supported by a comparison of the intended use, technological characteristics, dimensions, geometry, materials and configuration.

The manufacturer name, device name, 510(k) number and 510(k) clearance date of the predicate devices are provided below:

Manufacturer	Device Name	510(k) Number	Clearance Date
Implex Corp	Continuum Knee System	K882322	2/8/89
Osteonics	Series 7000	K940813	1/30/95
Smith & Nephew	Genesis II	K951987	8/22/95
Howmedica	Duracon	K926228	2/22/94



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 1998

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

Re: K981560
Implex Continuum Knee System: Porous Tibial Component
Regulatory Class: II
Product Code: JWH
Dated: April 30, 1998
Received: May 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.

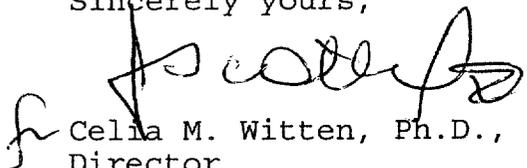
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

Page 3 - John A. Schalago, RAC

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,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

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):

K981560

Device Name:

Implex Continuum Knee Porous Tibial Component

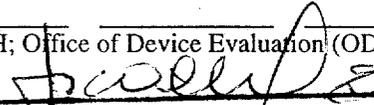
Indications For Use:

The Continuum Knee System (CKS):Porous Tibial Component is intended for use in the total knee joint where severe degeneration, trauma, or pathology of the knee indicates cemented total knee arthroplasty. The CKS is indicated for:

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

(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

K981560

Prescription Use _____
(Per 21 CFR 801.109)

OR...

Over-The-Counter Use _____

(Optional Format I-2-96)