

FEB 1 1999

K984291

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Implex Continuum Knee System® Cobalt Chromium Alloy Tibial Component**

**Submitter Name:** Implex Corp.  
**Submitter Address:** 80 Commerce Drive  
Allendale, New Jersey 07401-1600  
**Contact Person:** John Schalago or Robert Poggie  
**Phone Number:** (201) 818-1800  
**Fax Number:** (201) 818-0567  
**Date Prepared:** November 24, 1998  
**Device Trade Name:** Implex Continuum Knee System® Cobalt Chromium Alloy Tibial Component  
**Device Common Name:** Tibial Component, Cemented  
**Classification Number and Name:** Prosthesis, Knee, Femorotibial, Semi-Constrained, Cemented, Metal/Polymer 21 CFR § 888.3530

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**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 Continuum Knee System® Cobalt Chromium Alloy Tibial component is a fixed keel tibial tray manufactured from cast Cobalt Chromium Alloy. The Continuum Knee System® Cobalt Chromium Alloy Tibial is intended for cemented use only. This tibial component is available in 6 size options and is compatible with Continuum Knee System® Tibial Inserts. Continuum Knee System tibial inserts are manufactured from UHMWPE (ASTM F648) and are available in eight sizes (thickness), 10 – 26 mm.

***510(k) Premarket Notification-Continued***

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- Indications for Use:** The Continuum Knee System® Cobalt Chromium Alloy Tibial Component is intended for use where severe degeneration, trauma, or pathology of the knee joint indicates cemented total kncc arthroplasty.
- Device Technological Characteristics and Comparison to Predicate Device:** The Continuum Knee System® Cobalt Chromium Alloy Tibial Component incorporates design and technological characteristics of several commercially available titanium alloy and cobalt-chromium alloy fixed keel tibial component.
- Materials Comparison:** The change from titanium alloy to cobalt-chromium alloy does not effect safety or effectiveness of the Continuum Knee System Tibial components.
- Conclusion:** The Implex Continuum Knee System® Cobalt Chromium Alloy Tibial Component is substantially equivalent to the identified predicate devices.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K984291  
Implex Continuum Knee System® Cobalt  
Chromium Alloy Tibial Component  
Regulatory Class: II  
Product Code: JWH  
Dated: November 25, 1998  
Received: December 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.

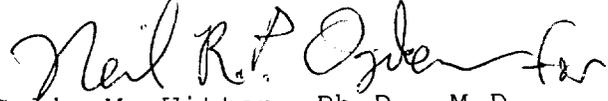
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the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

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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):

K984291

Device Name:

Indications For Use:

The Continuum Knee System® Cobalt-Chromium Alloy Tibial Component is intended for use where severe degeneration, trauma, or 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)

*NRPO*

**(Division Sign-Off)**  
**Division of General Restorative Devices**  
510(k) Number K984291

Prescription Use X  
(Per 21 CFR 801.109)

OR...

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

(Optional Format 1-2-96)