JUL 14 1999

K991869

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Implex Cobrex Hip Stem

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:	May 28, 1999
Device Trade Name:	Implex Cobrex Hip System, Femoral Component
Device Common Name:	Hip Prosthesis, Femoral Component Cemented or Uncemented
Classification Number and Name:	21 CFR § 888.3360

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 Implex Cobrex Hip Stem, cemented, is a modular femoral hip stem manufactured from forged cobalt chromium alloy conforming to ASTM F-799. The Cobrex hip stem has a 12/14 taper and is available in five stem sizes (10, 11, 12, 13, and 14) with proportionally increasing neck offsets (24 mm, 30 mm, and 36 mm). Also, the Cobrex hip stem is collared with a cobra type flange on the proximal section.

The Cobrex Hip Stem is intended for cemented use with Continuum® Hip Stem Components only.

Indications for Use:	The Implex Cobrex Hip Stem is intended for use where severe degeneration, trauma, or other pathology of the hip joint indicates cemented or hybrid total hip arthroplasty.
Device Technological Characteristics and Comparison to Predicate Device:	A comparison of technological characteristics of the subject and predicate devices supports a determination of substantial equivalence.
Performance Data:	Fatigue testing has been provided to demonstrate that the Cobrex hip stem will perform as intended.
Conclusion:	The Implex Cobrex Hip Stem is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

Mr. John A Schalago
Regulatory Affairs Manager
Implex® Corp.
80 Commerce Drive
Allendale, New Jersey 07401-1600

Re: K991869
Trade Name: Cobrex Hip Stem
Regulatory Class: II
Product Code: JDI
Dated: May 28, 1999
Received: June 1, 1999

Dear Mr. Schalago:

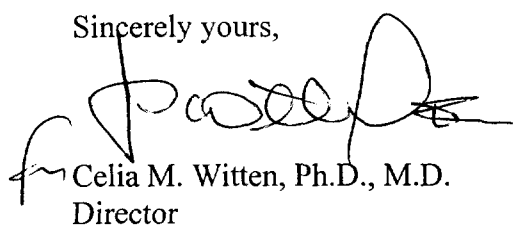
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

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

510(k) Number (if known): K991869

Device Name: Cobrex Hip Stem

Indications For Use:

The Implex Cobrex Hip Stem is intended for use where severe degeneration, trauma, or other pathology of the hip joint indicates cemented or hybrid total hip 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 K991869