JUN 11 1999

K990183

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Implex Alumina Femoral Head

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:	January 11, 1999
Device Trade Name:	Implex Alumina Femoral Head
Device Common Name:	Ceramic femoral head
Classification Number and Name:	21 CFR § 888.3353

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 Alumina Femoral Head is a ceramic femoral head. The Implex Alumina Femoral Head is offered in a 28 mm OD with +0, +3, and +6 neck off-set lengths, and is intended for use with all legally marketed Continuum Hip System Femoral Components with a 12/14 locking taper.

Indications for Use:

The Implex Alumina Femoral Head is intended to provide articulation in total hip procedures in cases of:

1. Severely disabled joints as a result of degenerative arthritis or avascular necrosis.
2. Secondary revision of a previously unsuccessful femoral component or total hip replacement.
3. Other hip problems where clinical experience has shown that alternative modes of treatment are less likely to achieve satisfactory results.
4. Fracture dislocation of the hip or irreducible fractures in which adequate fixation cannot be obtained.
5. Non-Union of femoral neck or head fractures.
6. Salvage of a failed primary or secondary total hip or hemi-hip arthroplasty.

Device Technological Characteristics and Comparison to Predicate Device:

A comparison of device characteristics, materials, intended use and indications for use to commercially available ceramic femoral heads provided in this premarket notification support the determination that the Implex Alumina Femoral Head is substantially equivalent to legally marketed ceramic head components.

Performance Data:

Mechanical test data provided in this premarket notification demonstrates that the Alumina Femoral Head will perform as intended.

Conclusion:

The Implex Alumina Femoral Head 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

JUN 11 1999

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

Re: K990183
Trade Name: Implex Alumina Femoral Head
Regulatory Class: II
Product Code: LZO
Dated: April 23, 1999
Received: April 26, 1999

Dear Dr. Poggie:

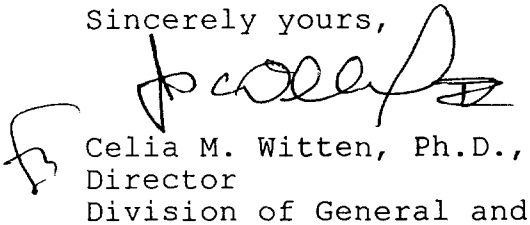
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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): K990183

Device Name: Implex Alumina Femoral Head

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(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 K990183

Prescription Use (Per 21 CFR 801.109) Yes OR... Over-The-Counter Use No

(Optional Format 1-2-96)