

JUN 1 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**Implex Radial Head Replacement System**

Submitter Name: Implex Corp.

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

Contact Person: John Schalago or Robert Poggie, Ph.D.

Phone Number: (201) 818-1800

Fax Number: (201) 818-0567

Date Prepared: April 19, 1999

Device Trade Name: Radial Head Surface Replacement

Device Common Name: Elbow joint humeral (hemi-elbow) prosthesis

Classification Number and Name: 21 CFR § 888.3170

**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 Radial Head Replacement System is a modular prosthesis consisting of a metallic head and a Hedrocel porous tantalum stem. The metallic head component is offered in three diameter options of 16, 21, and 26 mm, each with 4 head extension lengths. The articulating surface of the head component is offered in Co-Cr-Mo alloy. The stem component is offered in three cross sectional sizes of 7, 9, and 11 mm, with corresponding stem lengths of 23, 30, and 37 mm, respectively. All stem size options are compatible with all head size options. The Implex Radial Head Replacement System is a modular system, and the metallic head must be inter-operatively cemented to the Hedrocel stem using PMMA bone cement.

510(k) Summary of Safety and Effectiveness, Continued

Indications for Use:	<p>The Implex Radial Head Replacement System is indicated for:</p> <ul style="list-style-type: none">• Cemented Use Only.• Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:<ul style="list-style-type: none">-Joint destruction and/or subluxation.-Resistance to conservative treatment.• Primary replacement after fracture of the radial head.• Symptomatic sequelae after radial head resection.• Revision following failed radial head arthroplasty.
Predicate Device Information:	<p>The Implex Radial Head Replacement System is substantially equivalent to Wright Medical Technology, <i>Metallic Radial Heads</i>, and the Avanta Orthopedics, <i>Avanta RH™</i>.</p>
Device Technological Characteristics and Comparison to Predicate Device:	<p>A comparison of device characteristics (materials, design, configuration, and indications for use) included in this 510(k) Premarket Notification supports a substantial equivalence determination.</p>
Performance Data:	<p>Performance testing of the cemented modular assembly was performed, and the results indicate that the assembly possesses a high degree of mechanical integrity. Additionally, the Implex Radial Head is manufactured from materials with known performance characteristics (MAF #920) and properties which are typically used in total joint arthroplasty.</p>
Conclusion:	<p>The Implex Radial Head Replacement System is substantially equivalent to the identified predicate devices.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1999

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

Re: K984290
Trade Name: Implex Radial Head Replacement System
Regulatory Class: II
Product Code: KWI
Dated: April 20, 1999
Received: April 21, 1999

Dear Mr. Schalago:

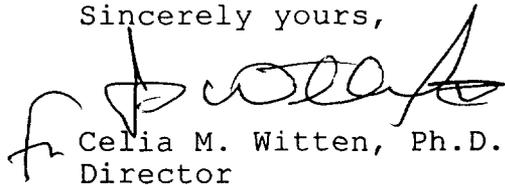
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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): K984290

Device Name: Implex Radial Head Replacement System

Indications For Use:

The Implex Radial Head Replacement System indications for use are as follows:

- For Cemented Use Only.
- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with:
 - a) Joint destruction and/or subluxation.
 - b) Resistance to conservative treatment.
- Primary replacement after fracture of the radial head.
- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR...

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984290