FEB 2 3 2000

510(k) Summary
Radial Head Prosthesis K 9 9 2 2 2 0

Submitter's name:	Smith & Nephew, Inc., Orthopaedic Division
Submitter's address:	1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number:	901/399-5153
Contact person:	Janet Johnson Green
Date summary prepared (amended):	February 1, 2000
Trade or proprietary device name:	Radial Head Prosthesis
Common or usual name:	Radial Head Implant
Classification name:	Title 21 CFR 888.3170 Elbow joint radial (hemi-elbow) prosthesis
Device Class:	Class II
Device Product Code and Panel Code:	87KWI Panel: Orthopaedics/87

Substantially Equivalent, Legally Marketed Predicate Devices:

Avanta Orthopaedics Radial Head Implant	Avanta Orthopaedics	(K982288)
Swanson Titanium Radial Head Implant	Wright Medical Technology	(K944507)
Implex Radial Head Replacement System	Implex Corporation	(K984290)

Subject device description:
The ***Radial Head Prosthesis***, like the predicate devices, includes various sizes of implants to accommodate the requirements of patient anatomy.

Subject device intended use:
The ***Radial Head Prosthesis*** is intended for replacement of the proximal end of the radius due to:

- degenerative or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and/or proximal radio-ulnar joint with:
  - joint destruction or subluxation visible on x-ray
  - resistance to conservative treatment
- primary replacement after fracture of the radial head
- symptomatic sequelae after radial head resection

The ***Radial Head Prosthesis*** is for single use only.

Technolocgical Characteristics:
The ***Radial Head Prosthesis*** is similar to legally marketed devices listed above in that all of these devices are indicated for radial head replacement and are similar in technological characteristics. The ***Radial Head Prosthesis*** is manufactured from Cobalt-Chrome, ASTM F 90, ISO 5832-5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2000

Ms. Janet Johnson Green
Manager, Clinical and Regulatory Affairs
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K992220
Trade Name: Radial Head Prosthesis
Regulatory Class: II
Product Code: KWI
Dated: February 7, 2000
Received: February 10, 2000

Dear Ms. Green:

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 control provisions of the Act. The general control 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Russell Vaga

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992220

Device Name: ***Radial Head Prosthesis***

Indications for Use:

The Radial Head Prosthesis is intended for replacement of the proximal end of the radius due to degenerative or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and/or proximal radio-ulnar joint involving joint destruction or subluxation visible on x-ray; resistance to conservative treatment; primary replacement after fracture of the radial head; and symptomatic sequelae after radial head resection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992220

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 601.109)