JUL 27 2000

K001385

510(k) Summary

Device: Howmedica Osteonics Radial Head Prosthesis

The Howmedica Osteonics Radial Head Prosthesis is a highly polished ulnar bearing surface with a distal stem. The radial head prosthesis is available in a variety of sizes ranging from 8mm to 11mm small and 9mm to 15mm medium components.

The Howmedica Osteonics Radial Head Prosthesis is indicated for replacement of the proximal end of the radius in cases of rheumatoid arthritis; degenerative or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint involving joint destruction and/or subluxation visible on x-ray; resistance to conservative treatment; fracture of the radial head; and symptomatic sequela after radial head resection. It is also indicated for use in revision procedures following failed radial head arthroplasty. This device is intended for cemented use only.

The radial head prosthesis will be fabricated from Vitallium® Alloy which complies to ASTM standard F 1537.

The substantial equivalence of the Howmedica Osteonics Radial Head Prosthesis is based upon equivalence in intended use, materials, design, and operational principles to the Wright Medical Technology, Inc. Metallic Radial Head Implants (K944507), the Avanta Orthopaedics, Inc Radial Head Implant (K982288) and the Smith & Nephew, Inc. Radial Head Prosthesis (K992220).

For information contact: Jennifer A. Daudelin
Regulatory Affairs
Howmedica Osteonics Corp.
359 Veterans Boulevard
Rutherford, NJ 07070
(201) 507-7283

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2000

Ms. Jennifer A. Daudelin
Regulatory Affairs
Howmedica Osteonics Corporation
359 Veterans Boulevard
Rutherford, New Jersey 07070

Re: K001385
Trade Name: Howmedica Osteonics Radial Head Prosthesis
Regulatory Class: II
Product Code: KWI
Dated: May 1, 2000
Received: May 2, 2000

Dear Ms. Daudelin:

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,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001385

Indications for Use

510(k) Number (if known): K001385

Device Name: Howmedica Osteonics Radial Head Prosthesis

Indications for Use:

The Howmedica Osteonics Radial Head Prosthesis is indicated for replacement of the proximal end of the radius in cases of rheumatoid arthritis; degenerative or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint involving joint destruction and/or subluxation visible on x-ray; resistance to conservative treatment; fracture of the radial head; and symptomatic sequela after radial head resection. It is also indicated for use in revision procedures following failed radial head arthroplasty. This device is intended for cemented use only.

(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)

Donna R Jackner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001385