SEP 13 1999

Attachment 2

K991915

510(k) Summary

Summary

Company: Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002
Date: June 7, 1999
Trade Name: Modular Radial Head
Common Name: Radial Head Prosthesis
Predicate Device: Metallic Radial Head Implant

Description/Intended Use:
The Modular Radial Head is manufactured from Cobalt Chrome (ASTM F 1537) . The stem is designed to be a two-piece modular design that is assembled at the time of implantation. The proximal portion of the head is concave and has rounded contours. The head and stem are available in standard sizes and +2 and +4 configurations.

Use of the Modular Radial Head Implants may be considered for :

- 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 visible on x-ray; and/or
  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.

The Modular Radial Head was declared substantially equivalent to the predicate devices. Mechanical test data demonstrated that it meets the requirements cited in the FDA Guidance Documents.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 1999

Ms. Lynne Witkowski
Regulatory Affairs Associate
Wright Medical Technology Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K991915
Trade Name: Modular Radial Head
Regulatory Class: II
Product Code: KWI
Dated: June 4, 1999
Received: June 7, 1999

Dear Ms. Witkowski:

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 at (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

Attachment 3

Indications for Use Statement

510(k) Number
(if known) K991915

Device Name **Modular Radial Head**

Indications for Use

Intended Use

Use of the Modular Radial Head Implants may be considered for :

- 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 visible on x-ray; and/or
  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) X OR Over-The Counter Use ____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991915