

NOV 6 1998

K983141

510K Summary**Capitello-Condylar Total Elbow Prosthesis**

November 2, 1998

1. Submitter

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, MA 02767
Deana Boushell, Regulatory Affairs Specialist, (508) 828-3107

2. Device Name

Proprietary Name: Capitello-Condylar Total Elbow Prosthesis
Common Name: Elbow Prosthesis
Classification Name: Elbow joint metal/polymer semi-constrained
cemented prosthesis
Regulatory Class: Class II, per CFR § 888.3160

3. Intended Use

The Capitello-Condylar Total Elbow Prosthesis is indicated for arthroplasty of the elbow in patients suffering from rheumatoid arthritis with intractable elbow pain, limited motion, and radiographically identifiable destruction, with relative preservation of bony stock. It is also indicated for use in certain older post-traumatic or osteoarthritic patients where a relatively low activity level is anticipated. This device is intended for cemented use.

4. Device Description

The Captiello-Condylar Total Elbow Prosthesis is an elbow replacement which relies on existing soft tissue structures such as the medial collateral ligament and triceps tendon for support and stability. The Humeral component is composed of cobalt-chromium-molybdenum (Co-Cr-Mo) alloy and has an intramedullary stem for fixation. The Ulnar component is composed of Co-Cr-Mo, with an articulating surface of ultra-high molecular weight polyethylene (UHMWPE). The device is designed to rely on soft tissue structures to support and absorb the forces which would otherwise be transmitted to the prosthesis, cement, or bone. The device is intended for use with bone cement.

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Capitello-Condylar Total Elbow Prosthesis

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5. Predicate Device Comparison

The Capitello-Condylar Total Elbow Prosthesis is substantially equivalent in terms of intended use, materials, design, manufacturing, and function to the Pre-Amendment Capitello-Condylar Elbow System. Modifications to the UHMWPE used in the manufacture of some of the system components do not represent a significant change to the safety and effectiveness of the device.

6. Device Testing Summary

Extensive evaluation testing of the calcium stearate free UHMWPE indicates that the material meets or exceeds all current specifications for the material. In addition, results of both mechanical property and device function testing show that the material performs as well as or better than the UHMWPE currently being used.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 6 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Deana M. Boushell, RAC
Regulatory Affairs Specialist
Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K983141
Capitello-Condylar Total Elbow Prosthesis
Regulatory Class: II
Product Code: JDB
Dated: September 4, 1998
Received: September 8, 1998

Dear Ms. Boushell:

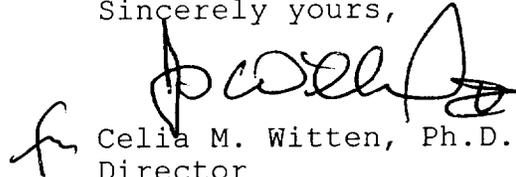
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

A handwritten signature in black ink, appearing to read 'C. Witten', with a large, stylized initial 'C' and a flourish at the end.

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

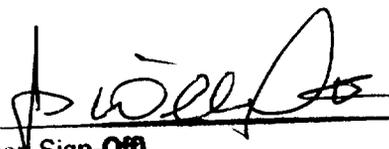
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CAPITELLO-CODYLAR TOTAL ELBOW PROSTHESIS INDICATIONS FOR USE

The Capitello-Condylar Total Elbow Prosthesis is indicated for arthroplasty of the elbow in patients suffering from rheumatoid arthritis with intractable elbow pain, limited motion, and radiographically identifiable destruction, with relative preservation of bony stock. It is also indicated for use in certain older post-traumatic or osteoarthritic patients where a relatively low activity level is anticipated. This device is intended for cemented use.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Director Sign-Off)

Division of General Restorative Devices

510(k) Number

K983141

Prescription Use Yes
(Per 21 CFR §801.109)

OR

Over-the-Counter Use No

(Optional Format 1-2-96)