

NOV - 5 1999

510(k) Summary
DePuy Total Elbow System

DePuy, Inc.
 700 Orthopaedic Drive
 Warsaw, IN 46581

A. Contact Person:

Janet G. Johnson, RAC
 Senior Regulatory Associate
 (219) 371-4907

B. Device Information:

Proprietary Name:	DePuy Total Elbow System
Common Name:	Elbow Prosthesis
Classification:	When used as a semi-constrained (unlinked elbow), it is a Class II device per 21 CFR §888.3160 When used as a constrained (linked), it is a Class III device per 21 CFR §888.3150
Product Code:	87 JDB – Prosthesis, Elbow, Semi-Constrained, Cemented (Class II) 87 JDC – Prosthesis, Elbow, Constrained, Cemented (Class III)

C. Indications for Use:

The DePuy Total Elbow System is indicated to reduce pain and improve the function and mobility of the affected joint in patients with a painful arthritic joint due to osteoarthritis, rheumatoid arthritis, or post traumatic arthritis and pathological fractures of the distal humerus in which adequate bone stock exists for the fixation of prosthetic components.

Total Elbow replacement may be considered for younger patients, if, in the opinion of the surgeon, an unequivocal indication for elbow replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and elbow joint loading can be assured. This included patients for whom an immediate gain of elbow mobility may lead to an expectation of significant improvement in the quality of their lives.

The DePuy Total Elbow System is intended for cemented use only.

D. Device Description:

The DePuy Total Elbow System is designed to be implanted as either an unlinked (semi-constrained) or linked (constrained) elbow. When the DePuy Total Elbow System is implanted as an unlinked elbow it relies on existing soft tissues, such as the medial collateral ligament and triceps tendon for support and stability. While the linked system is held together with the linked ulnar component and pin assembly, and is used when there is poor bone stock.

The DePuy Total Elbow System humeral stems are available in 100, 150, and 200mm lengths. The ulnar stems available in two lengths 60 and 80mm lengths, right and left, to accommodate different patient anatomy. Both the humeral and ulnar stems are intended for use with bone cement.

E. Substantial Equivalence:

The substantial equivalence of the DePuy Total Elbow System is substantiated by its similarity in indications for use, design, materials, sterilization and packaging to the current DePuy Mark II Elbow (K872084) and the Capitello-Condylar Total Elbow (K983141).

The determination of substantial equivalence for this device was based on a detailed device description, and conformance with voluntary performance standards.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Janet G. Johnson, RAC
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K992656
Trade Name: DePuy Total Elbow System
Regulatory Class: III
Product Code: JDC and JDB
Dated: August 6, 1999
Received: August 9, 1999

Dear Ms. Johnson:

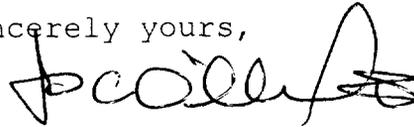
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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) K992656
Device Name DePuy Total Elbow System

Indications for Use

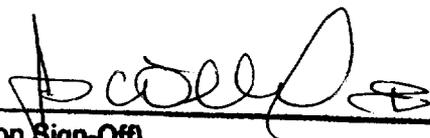
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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of **General Restorative Devices**
510(k) Number K992656

Prescription Use
(Per 21 CFR §801.109)

OR

Over-the-Counter Use

(Optional Format 1-2-96)