

K970544

SEP 12 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(k) CONTACT: Cheryl Hastings
Manager, Clinical Affairs

TRADE NAME: DePuy DuPont Orthopaedics
Finger Joint Prosthesis

COMMON NAME: Finger Joint Prosthesis

CLASSIFICATION: 888.3230 Finger joint, polymer, constrained
prosthesis

DEVICE PRODUCT CODE: 87 KYJ

**SUBSTANTIALLY
EQUIVALENT DEVICES:** ▲ Sutter Avanta MCP Joint Prosthesis
 ▲ Dow Corning Wright Swanson Finger Joint
 Implant

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy DuPont Orthopaedics (DDO) Finger Joint Prosthesis is a flexible, one-piece, hinged silicone elastomer implant designed to be implanted across the metacarpophalangeal (MCP) joint. The proximal and distal stems of the prosthesis form a 30° angle which mimics the approximate position of the joint when the hand is relaxed.

The DDO Finger Joint Prosthesis is indicated for cementless replacement of the metacarpophalangeal (MCP) joints of the finger where disabled by rheumatoid, degenerative or traumatic arthritis.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DDO Finger Joint Prosthesis is substantially equivalent to both the Dow Corning Wright Swanson Finger Joint Implant and the Sutter Avanta MCP Joint Prosthesis in that all of these implants are intended to replace the MCP joint when it is damaged due to rheumatoid, degenerative or traumatic arthritis. All of these implants are manufactured from silicone elastomer and all have a hinge design. The Swanson and Sutter implants are both designed as "straight" hinges while the DDO implant incorporates a 30° angle. Flexural fatigue testing shows that the DDO Finger Joint implants sustain the same or less damage than the Swanson or Sutter implants when cycled through a total of 90° of flexion/extension for 10 million cycles.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Cheryl Hastings
Manager, Clinical Affairs
DePuy, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K970544
Trade Name: DePuy DuPont Orthopaedics Finger
Joint Prosthesis
Regulatory Class: II
Product Code: KYJ
Dated: June 13, 1997
Received: June 16, 1997

Dear Ms. Hastings:

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.

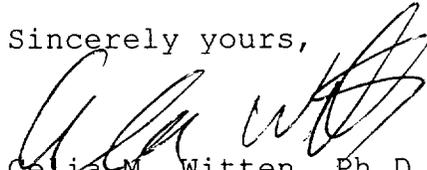
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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,



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

510(k) Number (if known) K970544

Device Name DePuy DuPont Finger Joint Prosthesis

Indications for Use:

The DePuy DuPont Finger Joint Prosthesis is indicated for cementless replacement of the metacarpophalangeal (MCP) joints of the finger where disabled by rheumatoid, degenerative or traumatic arthritis.

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K 970544

Prescription Use X

OR

Over-The Counter Use

(Per 21 CFR 801.109)