AUG 2 9 2000

K 001922

510(k) Summary
DePuy NeuFlex PIP Finger Prosthesis

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 NeuFlex PIP Finger
Common Name:	Finger Joint Prosthesis
Classification:	888.3230 Finger joint, polymer, constrained prosthesis
Product Code:	87 KYJ

C. *Indications for Use:*

The DePuy NeuFlex PIP Finger Prosthesis is indicated for cementless replacement of the proximal interphalangeal (PIP) joints of the finger where disabled by rheumatoid, degenerative or traumatic arthritis.

D. Device Description:

The DePuy NeuFlex PIP Finger Prosthesis is a flexible, one-piece silicone implant designed to be implanted across the PIP joint. The proximal and distal stems of the prosthesis form an angle, which mimics the approximate position of the joint when the hand is relaxed. This angle is the most obvious difference between the DePuy NeuFlex PIP Finger Prosthesis and other commercially available silicone finger joint prostheses, which have an unflexed, neutral angle of 0°.

E. Substantial Equivalence:

The substantial equivalence of the DePuy NeuFlex PIP Finger Prosthesis is substantiated by its similarity in indications for use, design, materials, sterilization and packaging to the current DePuy NeuFlex MCP Finger Prosthesis (K970544) and the Dow Corning Wright Swanson Finger Implant.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Janet G. Johnson, RAC
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K001922
Trade Name: DePuy NeuFlex PIP Finger
Regulatory Class: II
Product Code: KYJ
Dated: June 21, 2000
Received: June 23, 2000

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 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,

for 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

510(k) Number (if known) K001922

Device Name **DePuy NeuFlex PIP Finger**

Indications for Use

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K001922