JUL 14 1999

K991649

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR OF THIS 510(K):

DePuy, Inc.
a Johnson & Johnson company
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

MANUFACTURER:

DePuy OrthoTech™
1905 North McArthur Drive
Tracy, California 95376

510(K) CONTACT:

Sally Foust
DePuy Orthopaedics, Inc.
Sr. Regulatory Associate
(219) 372-7455; FAX (219) 267-7098
E-mail: sfoust2@dpyus.jnj.com

TRADE NAME:

DePuy® Rockwood™ Clavicle Pin

COMMON NAME:

Fracture Pin

CLASSIFICATION:

Class II per 888.3040, Smooth or threaded metallic bone fixation fastener

DEVICE CODE:

87 JDW

EQUIVALENT DEVICES:

DePuy Hagie & Modified Hagie Pins (pre-enactment)
DePuy Tibia Bolt (pre-enactment)
Onyx Medical Corp. (K903258) and O'Tec Corp. (K905347) Hagie Pins
Syntec-Trichung Knowles Pin (K983757)

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Rockwood Clavicle Pin consists of three sub-components, a pin and two nuts, and is provided pre-assembled. The clavicle pin has machine threads on one end and cancellous threads on the other end. The clavicle pin has a trocar point on the machine thread end and two nuts on the cancellous thread end. The pin is available in four diameters, 2.5, 3.0, 3.8 and 4.5mm, in one length, 152mm. The two locking nuts have slightly varying outer diameters. One nut is tightened on the pin to compress the fracture and prevent pin migration. The second nut is used to lock the first nut in place. The two sub-component nuts are also available separately.

The DePuy Rockwood Clavicle Pin is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject Rockwood Clavicle Pin is similar in design, material and intended use to the pre-enactment DePuy Hagie/modified Hagie Pins. All are trocar pointed, threaded pins manufactured from stainless steel that are indicated for use as the bone fixation fastener in bone-to-bone fixation of fractures. One difference between the Rockwood Clavicle Pin and the Hagie Pins is that the Rockwood is designed with the trocar point located on the machine thread end of the pin whereas the pre-enactment Hagie Pins have the trocar point on the cancellous thread end of the pin. This design of the Rockwood Clavicle Pin provides the surgeon with a clavicle pin that can be inserted from either a medial or lateral direction whereas the pre-enactment Hagie pins can only be inserted from a lateral direction.

The subject Rockwood Clavicle Pin is also similar in design, material and intended use to the pre-enactment DePuy Tibia Bolt, FDA cleared Hagie Pins (K903258, K905347) and Syntec-Trichung Knowles Pin (K983757). All are trocar pointed, threaded pins manufactured from stainless steel that are indicated for use as the bone fixation faster in bone-to-bone fixation of fractures.

Published and unpublished literature documents the use of Hagie, modified Hagie, and Knowles pins in the treatment of clavicle fractures thereby justifying the use of the very similarly designed Rockwood Clavicle Pin in the clavicle.

Based on similarities of design, materials and intended use, DePuy believes that the subject Rockwood Clavicle Pin is substantially equivalent to pre-enactment devices and FDA cleared devices currently on the market.

The following table summarizes the similarities:

	Rockwood Clavicle Pin	**Pre-Enactment Hagie & Modified Hagie Pin**	**Pre-Enactment Tibial Bolt**	**K903258 K905347 Hagie Pins**	**K983757 Syntec-Trichung Knowles Pin**
Material	316L SS	316L SS	316L SS	316L SS	316L SS
Use	FX Fixation	FX Fixation	FX Fixation	FX Fixation	FX Fixation
Fracture Site	Clavicle	Multi	Tibia	Multi	Multi
Product Code	87 JDW	87 JDW	87 JDW	87 JDW	87 JDW
Threaded	Yes	Yes	Yes	Yes	Yes
Trocar Point	Yes	Yes	Yes	Yes	Yes
Sizes	5	2	1	NA	2
Nuts	2	1	2	NA	NA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

Ms. Sally Foust
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K991649
Trade Name: DePuy Rockwood Clavicle Pin
Regulatory Class: II
Product Code: JDW
Dated: May 12, 1999
Received: May 13, 1999

Dear Ms. Foust:

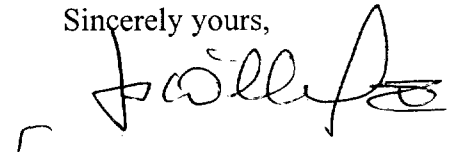
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known)_____

Device Name: DePuy® Rockwood™ Clavicle Pin

Indications for Use:

The DePuy Rockwood Clavicle Pin is intended to be used to repair an acute fracture, mal-union or nc union of the clavicle.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use___X_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991649