MAY 1 1 1998

K980595

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

DePuy, Inc.
700 Orthopaedic Drive, P.O. Box 988
Warsaw, IN 46581-0988

510(k) CONTACT:

Sally Foust
Regulatory Submissions Associate
DePuy Orthopaedics, Inc.
(219) 372-7455
FAX: (219) 267-7098
E-Mail: Sally_Foust@ccgate.depuy.com

TRADE NAME: DePuy OrthoTech Catera Suture Anchor

CLASSIFICATION NAME: Bone Fixation Staple

PRODUCT CODE: 79 JDR

SUBSTANTIALLY EQUIVALENT DEVICES: Zimmer Statak (K926384)
Stryker 2.7mm (K??????)
Mitek Surgical Products, Inc. (K902751, K920213)

INTENDED USE AND DEVICE DESCRIPTION:
The DePuy OrthoTech Catera Suture Anchor is intended for use in the shoulder for soft tissue re-attachment and capsular repair, including rotator cuff repairs, Bankart lesion repairs and SLAP lesion repairs.

The Catera Suture Anchor is a titanium 6Al-4V alloy, self-threading, cancellous screw available in diameters of 3.5mm and 4.5mm with a 0.030 inch diameter cylindrical eyelet at the end. The eyelet has two semicircular slots milled in the side of the head for suture clearance. *A 34 inch U.S.P. #2 nonabsorbable polyester suture is supplied pre-threaded through the eyelet with a single loop at the end of the screw.* The suture anchors that are supplied with needles attached to the suture will have a Sulzle needle #394475 swedged onto one or both ends of the suture.The suture anchor's tip threads are on an incline to the full diameter (body threads). The body threads which provide the main resistance to pullout are on a slight incline. The suture anchors are supplied either pre-loaded on a driver or separately.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The DePuy OrthoTech Catera Suture Anchor is substantially equivalent to the Zimmer Statak in that both of these devices are threaded suture anchors manufactured from Ti-6Al-4V alloy which are intended for soft tissue re-attachment in the shoulder.Mechanical testing in porcine and human cadaver bone showed that the pull-out loads for the Catera Suture Anchor were comparable to the pull-out loads for the Statak anchors. Mechanical testing in porcine bone showed that the maximum torque to failure results for the Catera Suture Anchor were better than those for the Statak anchors. Mechanical testing in porcine bone showed that the Catera Suture Anchor pull-out force results exceeded those for the Stryker and Mitek suture anchors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 1 1998

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

Re: K980595
Trade Name: DePuy OrthoTech Catera Suture Anchor
Regulatory Class: II
Product Code: MBI
Dated: February 13, 1998
Received: February 17, 1998

Dear Ms. Foust:

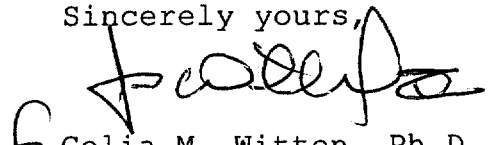
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Enclosure

510(k) Number (if known) K980595

Device Name DePuy OrthoTech Catera Suture Anchor

Indications for Use:

The DePuy OrthoTech Catera Suture Anchor is intended for use in the shoulder for soft tissue re-attachment and capsular repair, including rotator cuff repairs, Bankart lesion repairs and SLAP lesion repairs.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980595

Prescription Use X OR Over-The Counter Use ___
(Per 21 CFR 801.109)