

JUN 24 1997

April 15, 1997

K971453

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

*Submitter Name and Address:* OrthoTec, Inc.  
1053 Koloa Street  
Honolulu, HI 96816-5101

*Contact Person:* Dr. Patrick Bertranou  
(808) 737-3224

*Date Summary Prepared:* April 9, 1997

*Trade/Proprietary Name of Device:* OrthoTec K-Cap System

*Common or Usual Name of Device:* K-wire with Protective Tip

*Classification Name of Device:* Smooth or threaded metallic bone fixation fastener (21CFR 888.3040)

*Predicate Devices Under Which Substantial Equivalence is Being Claimed*

Kirchner Wire and Steinman Pins (K831005)

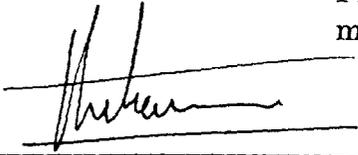
Ethicon Fixation Pins (K833952)

*Device Description:* The OrthoTec K-Cap System includes a K-wire, a protective cap (K-Cap), and applicator/handle for attachment of the cap to the K-wire.

*Intended Use of the Device:* The device is intended to provide fixation of bone fragments or for bone reconstruction, and the cap provides protection to neighboring tissues.

*Comparison with Predicate Device:* The K-Cap system is substantially equivalent to Kirchner Wire and Steinman Pins and to Ethicon Fixation Pins with respect to the design, materials, and intended use.

Signature: \_\_\_\_\_

  
Patrick Bertranou, M.D.  
President  
OrthoTec, Inc.

CONFIDENTIAL



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 24 1997

Patrick Bertranou, M.D.  
President  
OrthoTec, Inc.  
143 1/2 South Swall Drive  
Los Angeles, California 90069

Re: K971453  
OrthoTec K-Cap System  
Regulatory Class: II  
Product Code: HTY  
Dated: April 15, 1997  
Received: April 21, 1997

Dear Dr. Bertranou:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,

*Mare Afchroeder, MS, PT*  
for 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

10971453/A'

DUPLICATE

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510(k) Number (if known): K971453

Device Name: OrthoTec K-Cap System

Indications For Use:

The OrthoTec K-Cap System is intended to provide fixation of bone fragments or for bone reconstruction, while providing protection to neighboring tissues.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maree A. Schneider, MS PT for CMW

**(Division Sign-Off)**  
**Division of General Restorative Devices**  
510(k) Number K971453

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)