



916-342-4133
FAX: 916-343-4541

K972219

NOV 20 1997

27 August 1997

510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

- A. Classification name: Plate, fixation, bone
Common/usual name: Plate, bone plate, etc.
Proprietary name: Orthopedic Plate System

- B. Substantial equivalence: Howmedica, B.G. Compression System (K770128), DePuy, Inc. Distribution Center, Multiplicity of Products (K782123), Synthes, Synthes Reconstructive Plates "Y" Plates (K792291), Warsaw Orthopedic Company, Warsaw Orthopedic Bone Plate (K862224), Kirschner Medical Corp., Kirschner Small Fragment Fixation System (K864924), Acufex Microsurgical, Inc., Acufex Cannulated Screws, Washers, Bone Plates (K890641), Onyx Medical Corp., Broad Self-Compressing Plate (K903252), Surgical Implants, Inc., May Humerus Plates (K912936), Link America, Schwabe Radius Plates (K914803), The Anspach Effort, Inc., Anspach Mini-Plating System (K921338), Alphatec Manufacturing, Inc., Alphatec Compression and Reconstruction Plates (K922167), Howmedica, Luhr Pan Fixation System (K923861), Sofamor Danek Manufacturing, Inc., Reconstruction Plate System (K924085), Smith Nephew Richards, Inc., Variable Angular Hold Bone Plate System (K930480), Ace Medical

Company, Ace Universal Reconstruction Plate (K930592), Baumer Ortopedia Ltd., Baumer Plates (K930966), Onyx Medical Corp., Multiple Fragment Plate (K931687), Alphatec Manufacturing, Inc., Alphatec Compression and Reconstruction Plates (K933112), Synthes, Volar Distal Radial Plate (K953644).

- C. Device Description: The device is an assortment of various sizes and configurations of stainless steel bone plates.
- D. Intended use: The device is intended to be implanted for use in the fixation of long bone fractures and for long bone reconstructions.
- E. Technological characteristics: The Orthopedic Plate System is a standardly used device consisting of various sizes and configurations of stainless steel bone plates.

Sincerely,
FERGUSON MEDICAL

A handwritten signature in cursive script that reads "Frank Ferguson". The signature is written in black ink and is positioned below the typed name.

Frank Ferguson
Official Correspondent (FDA)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 1997

Mr. Frank Ferguson
Ferguson Medical
3407 Bay Avenue
Chico, California 95973

Re: K972219
Orthopedic Plate System
Regulatory Class: II
Product Code: HRS
Dated: October 10, 1997
Received: October 15, 1997

Dear Mr. Ferguson:

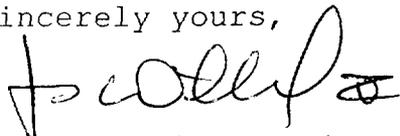
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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


h 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): K972219

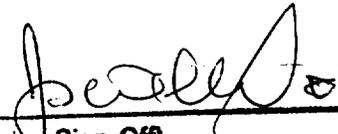
Device Name: Orthopedic Plate System

Indications For Use:

The device is intended to be implanted for use in the fixation of long bone fractures and for long bone reconstructions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972219

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)