SYNTHES®

K952272

JUL 31 1995

Attachment IX: Summary of Safety and Effectiveness Information [510(k) Summary]

SYNTHES (USA)
1690 Russell Road
Paoli, PA 19301

(610) 647-9700
Angela Silvestri
May 12, 1995

Device: Synthes Ti. Alloy 2.0 mm Cortex Screw is compared to Synthes 2.0 mm Cortex Screw (stainless steel).

Synthes Ti. Alloy 2.0 mm Cortex Screw is intended for fixation of fractures of the fingers. It has a hemispherical head, with a cruciform recess. It has buttress threads and a conical tip. The screw is available in multiple lengths, and is manufactured from Titanium-15% Molybdenum.

The Synthes preamendment 2.0 mm Cortex Screw is intended for fixation of fractures of the fingers . It has a hemispherical head, with a cruciform recess. It has buttress threads and a conical tip. The screw is available in multiple lengths, and is manufactured from 316L Stainless steel.

Synthes Ti. Alloy 2.0 mm Cortex Screw is at least equivalent to the Synthes 2.0 mm Cortex Screw, based on the results of the testing of both devices. This testing demonstrated that the Titanium-15% Molybdenum screws exhibit (1) failure torque properties that are comparable to 316L stainless steel screws, and (2) greater torsional ductility properties than 316L stainless steel screws.

The mechanical test data demonstrates that the relative torque properties of Titanium-15% Molybdenum screws are better than the published minimum torsional values for 316L stainless steel, according to ISO standard 6475.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1995

Ms. Angela J. Silvestri
Manager, Regulatory Affairs
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K952272
Ti. Alloy 2.0 mm Cortex Screw
Regulatory Class: II
Product Code: HWC
Dated: May 12, 1995
Received: May 15, 1995

Dear Ms. Silvestri:

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 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 practices, 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) 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.

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This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Ann C. Torres for

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health