



K963546

JUN 24 1997

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

Synthes (USA)
1690 Russell Road
Paoli, PA 19301

Contact: Angela Silvestri
(610) 647-9700
June 1997

The SMF Ti Alloy Bone Screws are compared to Synthes 1.0 mm, 1.3 mm, 2.0 mm and 2.4 mm bone screws, and are intended for craniofacial and mandibular trauma and reconstruction.

The screws are available in 1.5 mm and 2.0 mm diameters, and feature self-drilling, self-tapping tips and a square drive recess. The screws are available in 4 mm - 8 mm lengths in 1 mm increments and are manufactured from a titanium alloy.

The screws will be provided to the user non-sterile. Of course, non-sterile devices must be sterilized prior to use; moist heat sterilization is recommended.

It is our opinion that the SMF Ti Alloy Bone Screws are substantially equivalent to the predicate devices based on mechanical testing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN 24 1997

Re: K963546
Trade Name: SMF Titanium (TI) Alloy Bone Screws
Regulatory Class: II
Product Code: DZL
Dated: April 21, 1997
Received: April 21, 1997

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 (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 (Pre-market 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

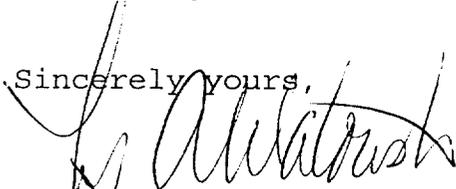
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



SYNTHES (USA)
1690 Russell Road
Post Office Box 1766
Paoli, Pennsylvania 19301
Telephone 610-647-9700

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510(k) Number (if known): K963546

Device Name: SMF Ti Alloy Bone Screws

Indications for use:

The SMF Ti Alloy Bone Screws are intended for craniofacial and mandibular trauma and reconstruction.

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

[Signature] concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K963546

Prescription Use OR

Over-The-Counter Use

(Per 21 CFR 801.109)