

JUN 15 2004

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3. 510(k) Summary:

K 046701

**Sponsor:**

Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
(610) 647-9700

**Contact:**

Sheri L. Musgnung

**Device Name:**

Synthes (USA) Hydroxyapatite (HA) Coated Schanz Screws

**Device Classification:**

21 CFR 888.3040 – “Smooth or threaded metallic bone fixation fastener”

**Predicate Device:**

Synthes Schanz Screws and Smith & Nephew Jet-X Half Pin.

**Description of Device:**

Synthes HA Coated Schanz Screws are available as self-drilling and non-self-drilling designs. The HA Coated Schanz Screws are available in a variety of diameters and lengths. The threaded portion of the schanz screw is coated with a very thin plasma sprayed coating of HA.

**Indications:**

Synthes HA Coated Schanz Screws are intended for use in an external fixation system for fracture fixation (open and closed); pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

**Material:**

Titanium and stainless steel

**Substantial Equivalence:**

Documentation is provided which demonstrates that the Synthes HA Coated Schanz Screws is substantially equivalent\* to other legally marketed devices.

\* The term “substantially equivalent” as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matter. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 15 2004

Sheri L. Musgnung  
Synthes (USA)  
1690 Russel Road  
P.O. Box 1766  
Paoli, Pennsylvania 19301

Re: K040701  
Trade/Device Name: Synthes Hydroxyapatite (HA) Coated Schanz Screws  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener.  
Regulatory Class: II  
Product Code: HWC  
Dated: March 16, 2004  
Received: March 17, 2004

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



*for* Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

2. Indications for Use

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510(k) Number (if known): K040701

Device Name: Synthes Hydroxyapatite (HA) Coated Schanz Screws

Indications for Use: Synthes Hydroxyapatite (HA) Coated Schanz Screws are intended for use with an external fixation system for fracture fixation (open and closed); pseudoarthrosis or non-union of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

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

Miriam C. Provost

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

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Synthes (USA) HA Coated Schanz Screw 510(k) Number K040701