MAR 2 1 2006

K 060408

3. 510(k) Summary

Sponsor:	Synthes (USA) 1302 Wrights Lane East West Chester, PA 19380
Contact:	Angela Silvestri Synthes (USA) 1230 Wilson Drive West Chester, PA 19380 (484) 356-9728
Device Name:	Norian SRS Bone Void Filler
Device Classification:	87 MQV – Class II – Filler, Bone Void, Calcium Compound
Device Description:	Norian SRS Bone Void Filler is an injectable, moldable, and biocompatible bone void filler. The Reactants Pack contains sterile powder (calcium phosphate) and a syringe that contains sterile solution (dilute sodium phosphate). The Reactants Pack is designed to be placed in a reusable mixer where the 2 components are mixed together to form a smooth, viscous paste that remains injectable for approximately 5 minutes at 18°-23°C / 64°- 73°F. At body temperature (37°C / 98.6°F), Norian SRS Bone Void Filler begins to harden after 2 minutes and sets in approximately 10 minutes. Norian SRS Bone Void Filler is slowly resorbed and replaced by bone over a period of years.
Indications for use:	Norian SRS Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. Norian SRS Bone Void Filler is intended to be placed or injected into bony voids or gaps of the skeletal system (the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. Norian SRS Bone Void Filler is <u>not intended for use in the spine</u> and should not be used in the presence of active or suspected infection.
Predicate Device	Norian SRS Bone Void filler, K011897
Substantial Equivalence Determination	Norian SRS Bone Void Filler is equivalent to the predicate device in terms of material composition, physical properties, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 1 2006

Synthes (USA)
c/o Ms. Angela J. Silvestri
Group Manager, Regulatory Affairs
1230 Wilson Drive
West Chester, Pennsylvania 19380

Re: K060408
Trade/Device Name: Norian SRS Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: February 15, 2006
Received: February 16, 2006

Dear Ms. Silvestri:

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.

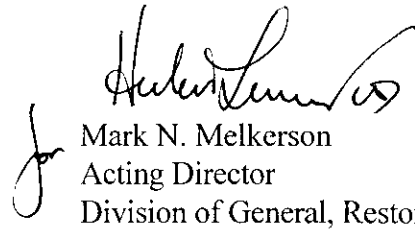
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2. **Indications for Use Statement**

510(k) Number (if known): K060408

Device Name: Norian SRS Bone Void Filler

Indications For Use:

Norian SRS Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. Norian SRS Bone Void Filler is intended to be placed or injected into bony voids or gaps of the skeletal system (the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Contraindications:

Norian SRS Bone Void Filler is not intended for use in the spine and should not be used in the presence of active or suspected infection

Prescription Use (Part 21 CFR 801 Subpart D) ✓ AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060408