8.5 ATTACHMENT V - 510K SUMMARY OF SAFETY AND EFFECTIVENESS

DEVICE

Norian® XR, USP is an injectable, moldable, biocompatible bone void filler. The reactants pack contains sterile powder (calcium phosphate) with $BaSO_4$ added for radiopacity and solution (dilute sodium phosphate). The Reactants Pack is designed to be placed in a reusable mixer where the components are mixed together to form a smooth, viscous paste that remains injectable for approximately 5 minutes at 18-23°C. Norian® XR begins to harden after 2 minutes and sets in approximately 10 minutes at body temperature (37°C). Norian® XR is slowly resorbed over a period of years. The 3cc, 5cc, 7.5cc, and 10cc Reactants Packs are provided sterile and are for single use only.

INDICATIONS

Norian® XR Calcium Phosphate Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. Norian® XR Calcium Phosphate Bone Void Filler is intended to be placed or injected into bony voids or gaps of the skeletal system (i.e., the extremities, spine 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 over a period of years and is replaced with bone during the healing process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 19 2002

Ms. Vikki M. Hoffman
Sr. RA Associate
SYNTHES Spine
1380 Enterprise Drive
West Chester, PA 19380

Re: K023862
Norian® XR
Regulatory Class: unclassified
Product code: MQV
Dated: November 18, 2002
Received: November 20, 2002

Dear Ms. Hoffman:

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 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). 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 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C Provost

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

8.3 ATTACHMENT III – INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023862

Device Name: Norian® XR (Extra Radiopaque) Calcium Phosphate Bone Void Filler (Norian® XR)

Indications for Use:

Norian® XR Calcium Phosphate Bone Void Filler is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. Norian® XR Calcium Phosphate Bone Void Filler is intended to be placed or injected into bony voids or gaps of the skeletal system (i.e., the extremities, spine 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 over a period of years and is replaced with bone during the healing process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR § 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number) K023862