SYNTHES®

APR 1 3 2006

K060443

3. 510(k) Summary

Sponsor:	Synthes (USA) 1302 Wrights Lane East West Chester, PA 19380
Contact:	Angela J. Silvestri (484) 356-9728
Device Name:	Norian CRS Fast Set Putty
Device Classification:	21 CFR 882.5300 – Methyl methacrylate for cranioplasty
Device Description:	Norian CRS Fast Set Putty is a moldable, thermally activated, biocompatible bone cement. Norian CRS Fast Set Putty is supplied in two containers; one container holds sterile powder (calcium phosphate) and the second container holds sterile solution (dilute sodium phosphate). When the powder and solution are mixed together with the provided cup and spatula, the resultant putty material is suitable for augmentation and restoration of the craniofacial skeleton. When fully cured, the composition formed closely approximates the mineral phase of bone. Norian CRS Fast Set Putty is gradually remodeled over time. This material is provided sterile and is for single use only.
Indications for use:	Norian CRS Fast Set Putty is intended for filling craniofacial defects in the restoration or augmentation of bony contours of the craniofacial skeleton (including fronto-orbital, malar, and mental areas) such as burr hole voids and other craniofacial defects, with a surface area no larger than $25cm^2$. Norian CRS Fast Set Putty is not intended for use in the spine and should not be used in the presence of active or suspected infection.
Predicate Device	Norian CRS Fast Set Putty K012589
Substantial Equivalence Determination	This device is equivalent to the predicate 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

APR 13 2006

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

Re: K060443
Trade/Device Name: Norian CRS Fast Set Putty
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl methacrylate for cranioplasty
Regulatory Class: II
Product Code: GXP
Dated: February 16, 2006
Received: February 23, 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): _____

Device Name: Norian CRS Fast Set Putty

Indications For Use:

Norian CRS Fast Set Putty is intended for filling craniofacial defects in the restoration or augmentation of bony contours of the craniofacial skeleton (including fronto-orbital, malar, and mental areas) such as burr hole voids and other craniofacial defects, with a surface area no larger than $25cm^2$.

Contraindications:

Norian CRS Fast Set Putty 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) ___X___ 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 K060443