K073303

## 1. 510(k) Summary

JUL - 2 2008

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| **Sponsor:** | Synthes Biomaterials<br>1230 Wilson Drive<br>West Chester, PA 19380 |
| **Company Contact** | Jeffrey L. Dow, JD<br>Director, Clinical & Regulatory Affairs<br>Synthes Biomaterials<br>484 356 9720<br>dow.jeff@synthes.com |
| **Device Name:** | Norian Drillable™ Bone Void Filler and Norian Drillable™ *Fast Set Putty*™ |
| **Classification:** | Class II, 21 CFR §888.3045<br>Filler, bone void, calcium compounds. |
| **Product Codes** | MQV, OIS |
| **Predicate Devices** | Norian SRS Bone Void Filler (K011897)<br>Norian SRS *Fast Set Putty*™ (K041842)<br>Osteobiologics Polygraft™ Bone Graft Substitute (K030288)<br>Wright Medical MIIG II Bone Graft Substitute (K024336) |
| **Device Description:** | Norian Drillable Bone Void Filler and Norian Drillable *Fast Set Putty*™ are moldable, biocompatible bone void fillers with added reinforcing fibers. Norian Drillable Bone Void Filler and Norian Drillable *Fast Set Putty*™ are intended to be placed into bony voids or defects of the extremities or pelvis either before or after final fixation. The material can be drilled and tapped, and screws can be placed through it at any time during or after the setting process. When fully cured, the composition formed closely approximates the mineral phase of bone.<br><br>The product is available in two delivery forms. Norian Drillable Bone Void Filler is an injectable paste that is mixed with an automatic mixer, and Norian Drillable *Fast Set Putty*™ is manually mixed with a cup and spatula.<br><br>*Norian Drillable* Bone Void Filler is provided in a sterile pouch (the "Reactants Pack"). The Reactants Pack is constructed of a clear-film outer pouch and a foil laminate inner pouch with an attached delivery syringe. The Reactants Pack contains sterile powder with fibers and is designed with an injection port for the purpose of adding the mixing solution to the pouch. The |

mixing solution is contained in the Solution Syringe, which is packaged separately.

The Reactants Pack is designed to be placed in a reusable mixer (the "Rotary Mixer") where the two components are mixed together to form a smooth, viscous paste. The paste remains injectable for approximately 5 minutes at 18°-23°C / 64°-73°F. At body temperature (37°C / 98.6°F), Norian Drillable Bone Void Filler begins to harden after 2 minutes and sets in approximately 10 minutes. Norian Drillable Bone Void Filler is slowly resorbed over a period of years and replaced with bone during the healing process.

*Norian Drillable Fast Set Putty*™ is supplied in two containers. The mixing cup holds sterile powder with fibers and the Solution Syringe holds sterile solution. When the powder and solution are mixed together with the provided cup and spatula, the resultant putty material can be manipulated for two minutes at 18°-23°C / 64°-73°F.

At body temperature (37°C / 98.6°F), Norian Drillable *Fast Set Putty* begins to harden after 2 minutes and sets in approximately 3 to 6 minutes. Norian Drillable *Fast Set Putty*™ is slowly resorbed over a period of years and replaced with bone during the healing process.

**Intended Use:**

Norian Drillable Bone Void Filler and Norian Drillable *Fast Set Putty*™ are intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. 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 Drillable Bone Void Filler and Norian Drillable *Fast Set Putty*™ can be used as an adjunct to conventional rigid hardware fixation by supporting bone fragments during the surgical procedure. Once the material is set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Bone Void Filler and Norian Drillable *Fast Set Putty*™ are intended to be placed into bony voids either before or after final fixation.

**Substantial Equivalence:** Documentation is provided that demonstrates that Norian Drillable is substantially equivalent[1] to other legally marketed devices.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug & Cosmetic Act, as amended, and as applied under 21 CFR Part 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalence under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein, shall be construed as an admission against interest under the U.S. patent laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2008

Synthes (USA)
c/o Mr. Jeffrey L. Dow, JD
Director, Clinical and Regulatory Affairs, Biomaterials
1302 Wrights Lane East
West Chester, PA 19380

Re: K073303
Device Name: Norian Drillable Bone Void Filler and Norian Drillable Fast Set Putty
Regulation Number: 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: OIS, MQV
Dated: June 3, 2008
Received: June 4, 2008

Dear Mr. Dow:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Contraindications section of the device's labeling.

The safety and effectiveness of this device for use in the spine has not been established.

Use of this device is contraindicated in the spine, including use in the pedicle, as this could be associated with leakage of the device material into the bloodstream, which could cause serious adverse events, including death.

Furthermore, the indications for use and contraindications for use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of at least 10 point font, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K073303

Device Name: Norian Drillable Bone Void Filler and Norian Drillable Fast Set Putty

Indications For Use:

Norian Drillable Bone Void Filler and Norian Drillable *Fast Set Putty*™ are intended for bony voids or defects of the extremities and pelvis that are not intrinsic to the stability of the bony structure. 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 Drillable Bone Void Filler and Norian Drillable *Fast Set Putty*™ can be used as an adjunct to conventional rigid hardware fixation by supporting bone fragments during the surgical procedure. Once the material is set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Bone Void Filler and Norian Drillable *Fast Set Putty*™ are intended to be placed into bony voids either before or after final fixation.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milleman

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



**510(k) Number** K073303