



K102722

JAN 27 2011

Page 1 of 2

2. 510(k) Summary

Sponsor: Synthes Biomaterials
1230 Wilson Drive
West Chester, PA 19380

Company Contact: Jeffrey L. Dow, JD
Director, Clinical & Regulatory Affairs
Synthes Biomaterials
484 356 9720
dow.jeff@synthes.com

Device Name: Norian Drillable™ Inject and Norian Drillable™ Fast Set Putty™

Classification: Class II, 21 CFR §888.3045
Filler, bone void, calcium compounds.

Product Codes MQV, OIS

Predicate Devices Norian SRS Bone Void Filler and Norian SRS Fast Set Putty (K073303)

Device Description: Norian Drillable Inject and Norian Drillable Fast Set Putty are moldable, biocompatible bone void fillers with added reinforcing fibers. Norian Drillable Inject 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.

The product is available in two delivery forms. Norian Drillable Inject 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.

Norian Drillable Inject is provided in a sterile pouch (the "Rotary Pouch"). The Rotary Pouch is constructed of a clear-film outer pouch and a foil laminate inner pouch with an attached delivery syringe. The Rotary Pouch 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 Rotary Pouch 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 Inject begins to harden after 2 minutes and sets in approximately 10 minutes. Norian Drillable Inject 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 Inject 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 Inject and Norian Drillable Fast Set Putty can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject 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 equivalent⁴ to other legally marketed devices.

⁴ 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 and Cosmetic Act, as



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA)
c/o Mr. Jeffrey L. Dow, JD
Director, Clinical and Regulatory Affairs, Biomaterials
1230 Wilson Drive
West Chester, PA 19380

JAN 27 2011

Re: K102722
Device Name: Norian Drillable Inject and Norian Drillable Fast Set Putty
Regulation Number: 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: MQV, OIS
Dated: January 14, 2011
Received: January 18, 2011

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) 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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

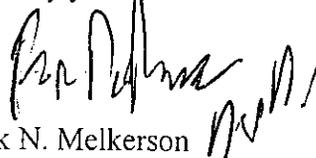
Page 2 – Mr. Jeffrey L. Dow, JD

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 advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



K102722

1. Indications for Use Statement

Norian Drillable Inject 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 Inject and Norian Drillable *Fast Set Putty* can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject 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 _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102722



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA)
c/o Mr. Jeffrey L. Dow, JD
Director, Clinical and Regulatory Affairs, Biomaterials
1230 Wilson Drive
West Chester, PA 19380

JAN 27 2011

Re: K102722
Device Name: Norian Drillable Inject and Norian Drillable Fast Set Putty
Regulation Number: 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: Class II
Product Code: MQV, OIS
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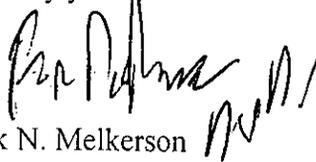
Page 2 – Mr. Jeffrey L. Dow, JD

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 advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



K102722

1. Indications for Use Statement

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Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102722



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center, WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 10, 2011

SYNTHES USA PRODUCTS LLC
1230 WILSON DRIVE
WEST CHESTER, PENNSYLVANIA 19380
UNITED STATES
ATTN: JEFFREY L. DOW, JD

510k Number: K102722

Product: NORIAN DRILLABLE INJECT, NORIA

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModer-nizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Device Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Synthes (USA)
c/o Mr. Jeffrey L. Dow, JD
Director, Clinical and Regulatory Affairs, Biomaterials
1230 Wilson Drive
West Chester, Pennsylvania 19380

NOV 16 2010

Re: K102722
Device Name: Norian Drillable Inject™ and Norian Drillable Fast Set Putty™
Dated: September 17, 2010
Received: September 21, 2010

Dear Mr. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based on the information you provide. To complete the review of your submission, (b)(4)

(b)(4)

The deficiency identified above represents the issue that we believe needs to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiency, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry

Page 2 - Mr. Jeffrey L. Dow, JD

Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment” at

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf>

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

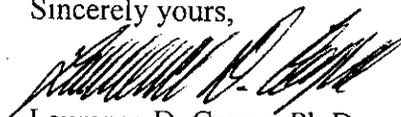
The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Nadine Y. Sloan at (301) 796-6430. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Laurence D. Coyne, Ph.D.
Chief, Restorative Devices Branch
Division of Surgical, Orthopedic and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 21, 2010

SYNTHES USA PRODUCTS LLC
1230 WILSON DRIVE
WEST CHESTER, PENNSYLVANIA 19380
UNITED STATES
ATTN: JEFFREY L. DOW, JD

510k Number: K102722

Received: 9/21/2010

Product: NORIAN DRILLABLE INJECT, NORIA

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff



CONFIDENTIAL: CONTAINS TRADE SECRET INFORMATION

K102722

September 17, 2010

Document Mail Center - WO66, Room 0609
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FDA CDRH DMC
SEP 21 2010
Received

Re: Special 510(k): Device Modification

Norian® Drillable Inject™ and Norian® Drillable Fast Set Putty™¹

Dear Sir/Madam:

These documents constitute a Special 510(k): Device Modification relating to the intent of Synthes (USA) to market its Norian Drillable Inject™ and Norian Drillable *Fast Set Putty*™ (collectively, "Norian Drillable Products"). As discussed in the attached submission, Synthes' Norian Drillable Products are identical in intended use, formulation, packaging and available product sizes and configurations to other commercially available Norian configurations, and therefore are substantially equivalent to them.

Synthes has previously submitted a Traditional 510(k) for these devices that was cleared by FDA on July 2, 2008, under K073303 (the "SE Letter")². As of the date hereof, no products that are the subject of that clearance have been introduced into interstate commerce in the U.S. **In all respects, except for the change in labeling proposed herein (which does not change the cleared indication for use), the Norian Drillable Products described in this submission are identical to those cleared in K073303.**

In its review of K073303, FDA determined that there was a reasonable likelihood that Norian Drillable Products would be used for an intended use not identified in the proposed label and that such use could cause harm. Therefore it concluded that:

¹ Norian Drillable Inject and Norian Drillable Fast Set Putty have in the past been known by other names. For example, in the predicate submission, K073303, Norian Drillable Inject was called "Norian Drillable Bone Void Filler". Both products have been known by other names as well. However, in this submission the two products involved, and their predicate counterparts, should be understood in each case to be the products in the heading to this cover letter, i.e., Norian Drillable Inject and Norian Drillable Fast Set Putty, even if they are identified differently.

² The entire SE letter is presented in Attachment 1.

K42



“... [I]n 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 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.”

Synthes has discovered that the labeling text that FDA has required cannot feasibly be included in “all labeling.” Although the text will fit on some of the labeling, some of the component packaging does not have sufficient surface area for a label large enough to accommodate the required text, in the required font size, displayed in “close proximity to the product name”, in a manner likely be to read and understood by relevant health care professionals.

Further, Synthes believes that including the full text on “all” of the labeling is not the optimum method for ensuring that the product is not misused. Synthes therefore submits this Special 510(k) in which it proposes a modification of the labeling requirements imposed in the SE Letter. This proposal, including Synthes’ rationale, is presented and discussed in Section 7 of this submission. **In all other respects, the Norian Drillable Products covered by this Special 510(k) are identical to those cleared in K073303.**

A Special 510(k) is appropriate for the proposed labeling changes because, consistent with FDA’s guidance on how to prepare a Special 510(k),³ the labeling modification sought herein does not (1) affect the intended use, or (2) alter the fundamental scientific technology of the device. Synthes believes that this new submission completely and accurately responds to all of FDA’s requirements for a Special 510(k) and that this submission therefore should be found to demonstrate the substantial equivalence of Norian Drillable Products to commercially available predicates.

³ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134573.htm#criteria>.





We consider our intent to market this device to be confidential commercial information. Synthes has not disclosed its intent to market this product to anyone other than collaborators or consultants under legally binding restrictions not to disclose this information to unauthorized persons. We have taken precautions to protect the confidentiality of this submission.

If you have any questions concerning this submission, please telephone me at 484 356 9720, or contact me by e-mail at dow.jeff@synthes.com. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'JD' with a stylized flourish.

Jeffrey L. Dow, JD
Director, Clinical & Regulatory Affairs
Synthes Biomaterials

/Attachments

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

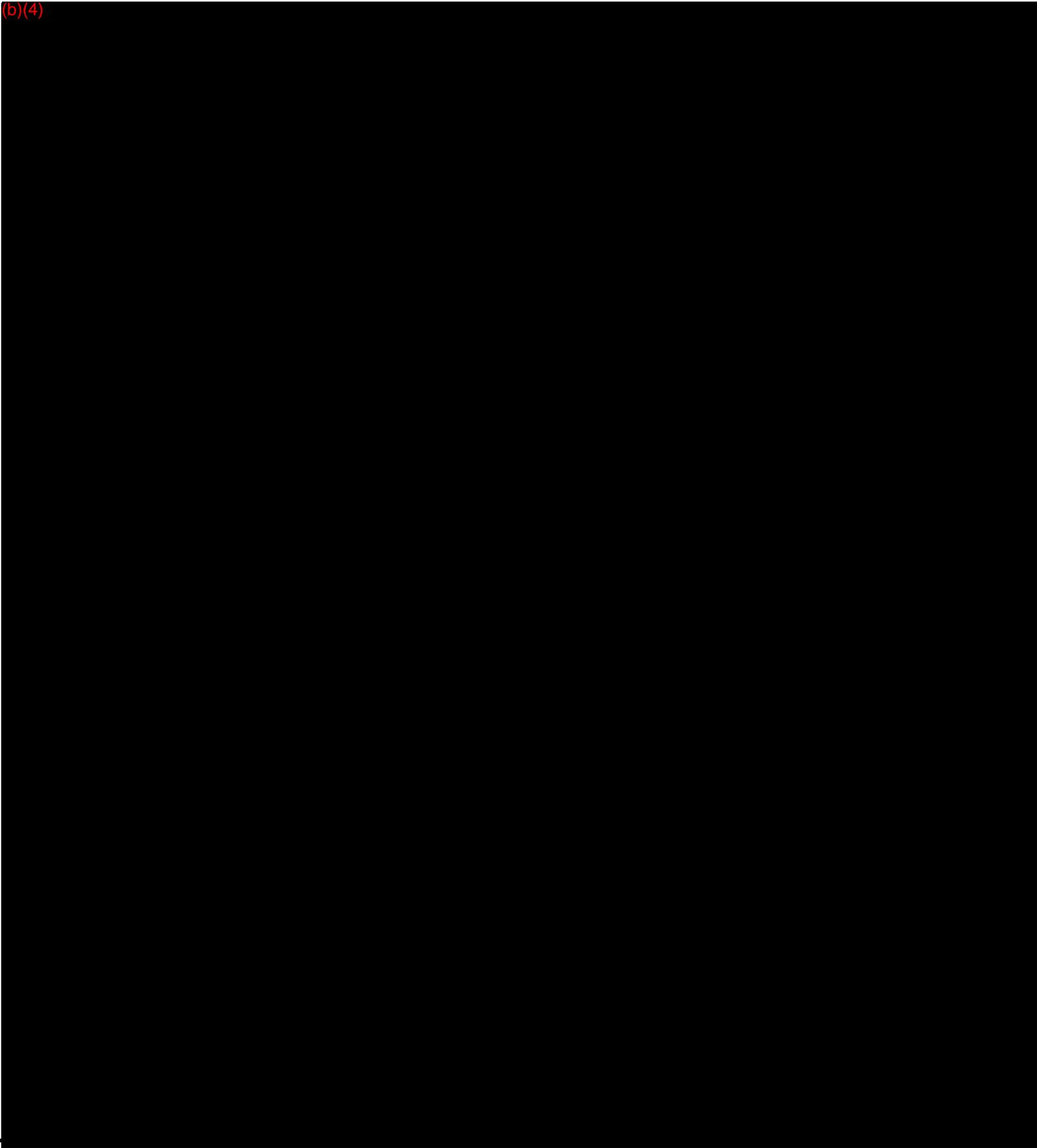
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) Synthes Spine L P P O BOX 0548 1690 RUSSELL ROAD PAOLI PA 19301 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****2622	2. CONTACT NAME Jeffrey Dow 2.1 E-MAIL ADDRESS dow.jeff@synthes.com 2.2 TELEPHONE NUMBER (include Area code) 484-3569720 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 484-3569682	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		

27-Jul-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

(b)(4)



DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 0910-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.
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Date of Submission 08/09/2010	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
----------------------------------	--------------------------------------	---

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Synthes USA Products LLC		Establishment Registration Number (if known) (b)(4)	
Division Name (if applicable)		Phone Number (including area code) 484 356 9720	
Street Address 1230 Wilson Drive		FAX Number (including area code) 484 356 9682	
City West Chester	State / Province PA	ZIP/Postal Code 19380	Country USA
Contact Name Jeffrey L. Dow, JD			
Contact Title Director, Clinical & Regulatory Affairs		Contact E-mail Address dow.jeff@synthes.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason (specify):					
SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Other Reason (specify):					
SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input checked="" type="checkbox"/> Other Reason (specify): Modification of labeling as required by Substantially Equivalent letter for K073303.					

SECTION E				ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS			
Product codes of devices to which substantial equivalence is claimed							Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	MQV	2	OIS	3	4	5	
5	6	7	8	9	10	11	

Information on devices to which substantial equivalence is claimed (if known)			
	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K073303	Norian Drillable Bone Void Filler and Norian Drillable Fast Set Putty	Synthes USA Products LLC
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Calcium salt bone void filler

	Trade or Proprietary or Model Name for This Device	Model Number
1	Norian Drillable Inject	1
2	Norian Drillable Fast Set Putty	2
3		3
4		4
5		5

FDA document numbers of all prior related submissions (regardless of outcome)					
1	K073303	2	3	4	5
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

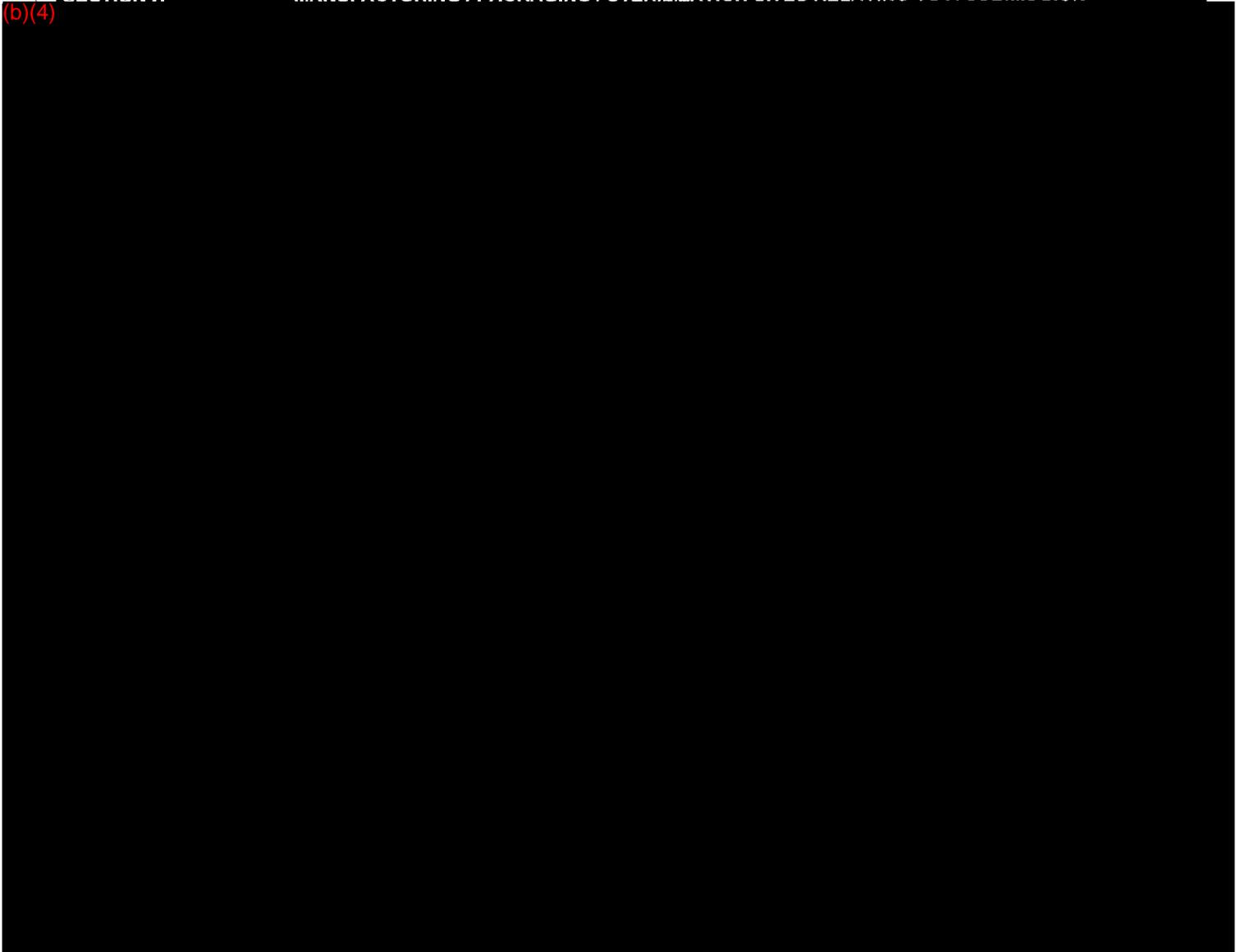
Product Code OIS, MQV	C.F.R. Section (if applicable) 21 CFR 888.3045	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel		

Indications (from labeling)
 Norian Drillable Inject 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 Inject and Norian Drillable Fast Set Putty can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject and Norian Drillable Fast Set Putty are intended to be placed into bony voids either before or after final fixation.

<p>Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.</p>	<p>FDA Document Number <i>(if known)</i></p>
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SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

(b)(4)



<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i>	
Street Address		FAX Number <i>(including area code)</i>	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
 Food and Drug Administration
 Office of the Chief Information Officer (HFA-710)
 5600 Fishers Lane
 Rockville, Maryland 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.



Document Mail Center - WO66, Room 0609
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Special 510(k) : Device Modification

Norian® Drillable Inject and Norian® Drillable Fast Set Putty

Submitted by:
Synthes Biomaterials
1230 Wilson Drive
West Chester, PA 19380

Contact Name:
Jeffrey L. Dow, JD
Director, Clinical &
Regulatory Affairs
Synthes Biomaterials
484 356 9720
dowj@synthes.com



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1. Indications for Use Statement

Norian Drillable Inject 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 Inject and Norian Drillable *Fast Set Putty* can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject and Norian Drillable *Fast Set Putty* are intended to be placed into bony voids either before or after final fixation.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



2. 510(k) Summary

Sponsor: Synthes Biomaterials
1230 Wilson Drive
West Chester, PA 19380

Company Contact Jeffrey L. Dow, JD
Director, Clinical & Regulatory Affairs
Synthes Biomaterials
484 356 9720
dow.jeff@synthes.com

Device Name: Norian Drillable™ Inject and Norian Drillable™ Fast Set Putty™

Classification: Class II, 21 CFR §888.3045
Filler, bone void, calcium compounds.

Product Codes MQV, OIS

Predicate Devices Norian SRS Bone Void Filler and Norian SRS Fast Set Putty (K073303)

Device Description: Norian Drillable Inject and Norian Drillable Fast Set Putty are moldable, biocompatible bone void fillers with added reinforcing fibers. Norian Drillable Inject 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.

The product is available in two delivery forms. Norian Drillable Inject 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.

Norian Drillable Inject is provided in a sterile pouch (the "Rotary Pouch"). The Rotary Pouch is constructed of a clear-film outer pouch and a foil laminate inner pouch with an attached delivery syringe. The Rotary Pouch 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 Rotary Pouch 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 Inject begins to harden after 2 minutes and sets in approximately 10 minutes. Norian Drillable Inject 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 Inject 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 Inject and Norian Drillable Fast Set Putty can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject 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 equivalent⁴ to other legally marketed devices.

⁴ 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 and 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 US patent laws or their application by the courts.



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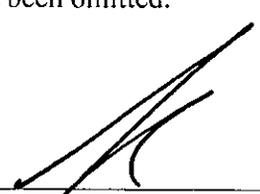
1. Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required By 21 CFR 807.87(k)]

I certify that, in my capacity as Director, Clinical & Regulatory Affairs for Synthes Biomaterials, I believe, to the best of my current knowledge, all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.



Jeffrey L. Dow, JD
September 17, 2010



2. Class III Summary and Certification

This section is not applicable.

3. Financial Certification or Disclosure Statement

This section is not applicable.

4. Declarations of Conformity and Summary Reports

A "Declaration of Conformity with Design Controls" is presented in **Attachment 5** of this submission.

5. Executive Summary and Device Description

Device Names

Norian Drillable Inject and Norian Drillable Fast Set Putty

5.1 Establishment Registration

Synthes USA Products LLC is registered with the Device Registration and Listing Branch of the U.S. Food and Drug Administration (FDA). The devices subject to this premarket notification are manufactured by Norian Corporation, 1230 Wilson Drive, West Chester, PA 19380 (b)(4)

5.2 Classification Information

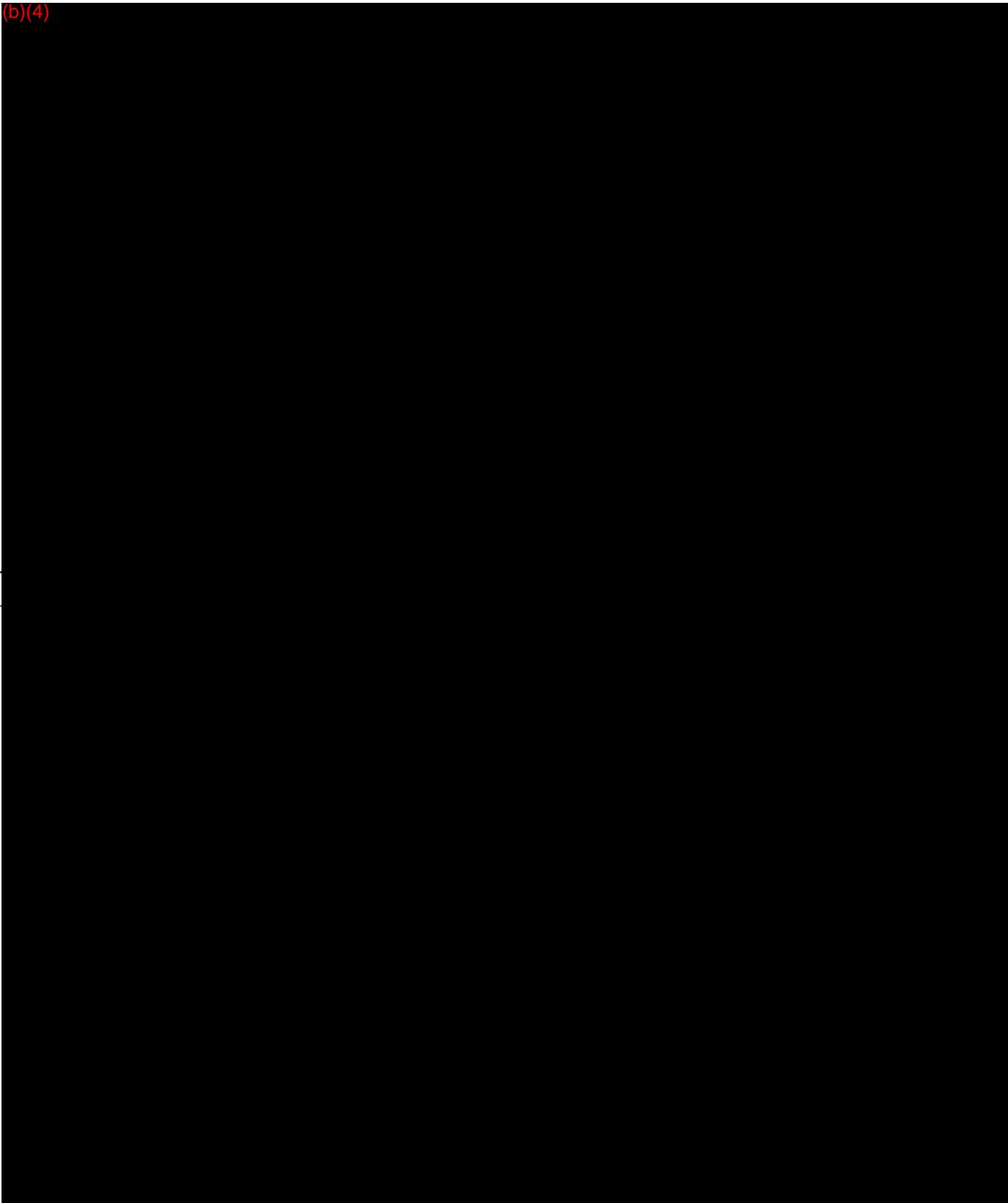
The classification of Norian Drillable Inject and Norian Drillable Fast Set Putty are Class II, per Title 21 of the Code of Federal Regulations (CFR), §888.3045, Filler, bone void, calcium compounds; Product Codes: MQV, OIS.

The accessories for Norian Drillable Inject and Norian Drillable Fast Set Putty are identical to the accessories for their predicates:

- Mixer, Class I, exempt per Title 21 CFR, §888.4210, Cement Mixer for clinical use; Product Code JDZ
- Delivery Device, Class I, exempt per Title 21 CFR, §888.4200, Cement dispenser; Product Code KIH
- Delivery Needles, Class I, exempt. These are not specifically classified but are similar to aspiration and injection needles as described in Title 21 CFR, §878.4800, Manual surgical instrument for general use; Product Code GAA.

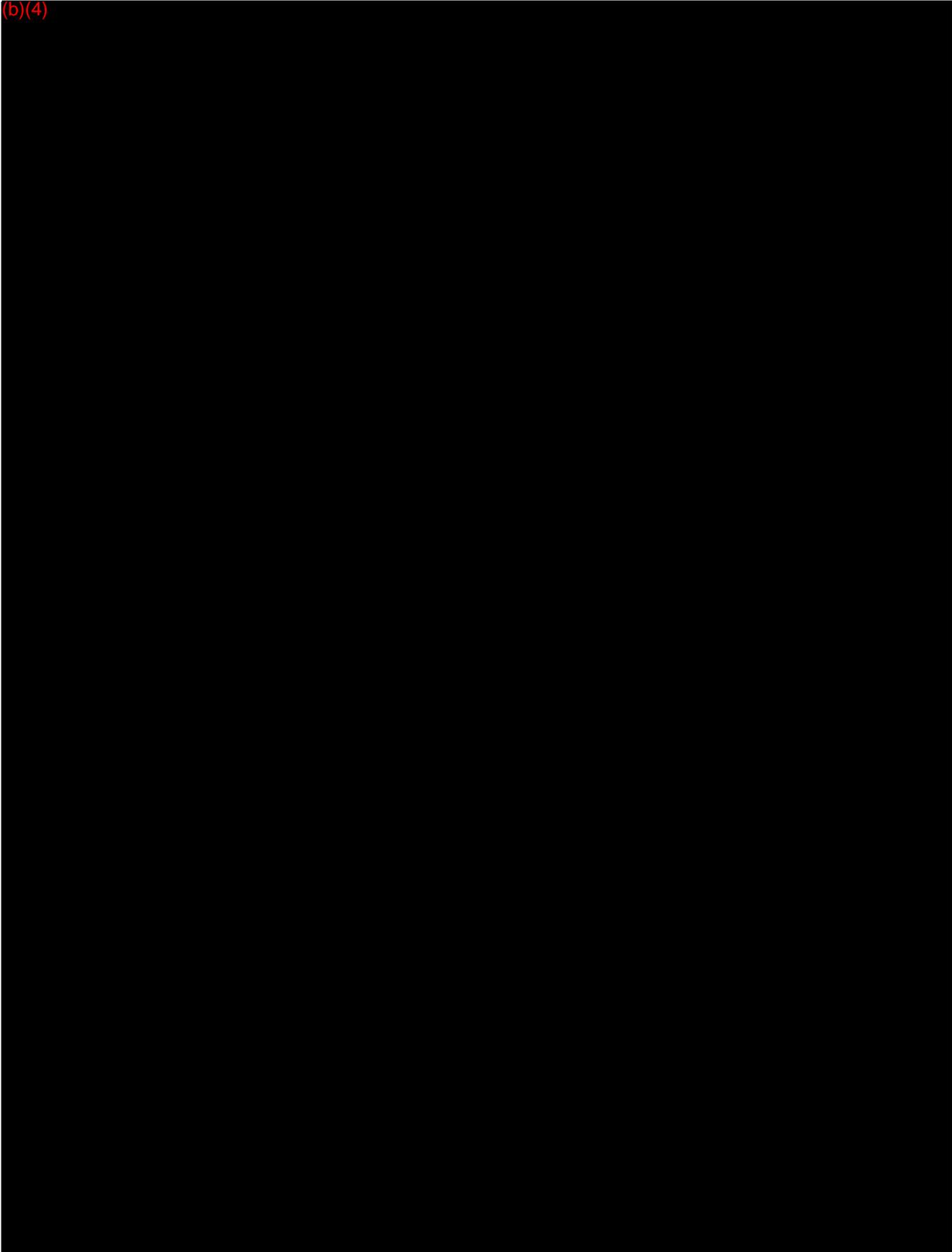


(b)(4)

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(b)(4)

6 Substantial Equivalence Discussion

In all respects, except for the change in labeling proposed herein, the Norian Drillable Products described in this submission are identical to those cleared in K073303, and, therefore, are substantially equivalent to them. Synthes does not rely in this submission on any recognized standards to demonstrate substantial equivalence. Section 7 describes and discusses the proposed modification in labeling.

7. Proposed Labeling

This submission proposes a modification to the labeling submitted by Synthes in K073303. Synthes' proposed modification, including reproduction in full size of each package label, product specific directions for use (DFU) for both Norian Drillable Products, a technique guide, and photographs of the packaging are all presented in **Attachment 3**.

(b)(4)

7.1. Background.

The remainder of the information in this section describes FDA's requirements for labeling of Norian Drillable Products, Synthes' proposed modified labeling, and the rationale for its implementation.

In its review of K073303, FDA determined that there was a reasonable likelihood that Norian Drillable Products would be used for an intended use not identified in the proposed label and that such use could cause harm. Therefore it concluded in its SE Letter that:

“... [I]n 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 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."⁶

The labeling as it is currently required by the SE Letter is presented in **Attachment 3**.⁷ As required, it is presented in **boldface** in 10 point type.⁸

First, Synthes agrees that the potential misuse that concerned FDA during its review of K073303 should be contraindicated in the labeling for Norian Drillable Products, and that the description of that harm required by FDA should be implemented as required by the SE Letter. We also agree that the whole of the language required by the SE Letter should be implemented in the DFUs and Technique Guides for each Norian Drillable Product.

However, it believes that its use in full on each element *of the packaging* is impractical and, more important, inadvisable as a protection to healthcare professionals and patients. Synthes believes that a subset of that required labeling on each element of the packaging would more forcefully and effectively warn against the off-label use of which FDA is concerned.

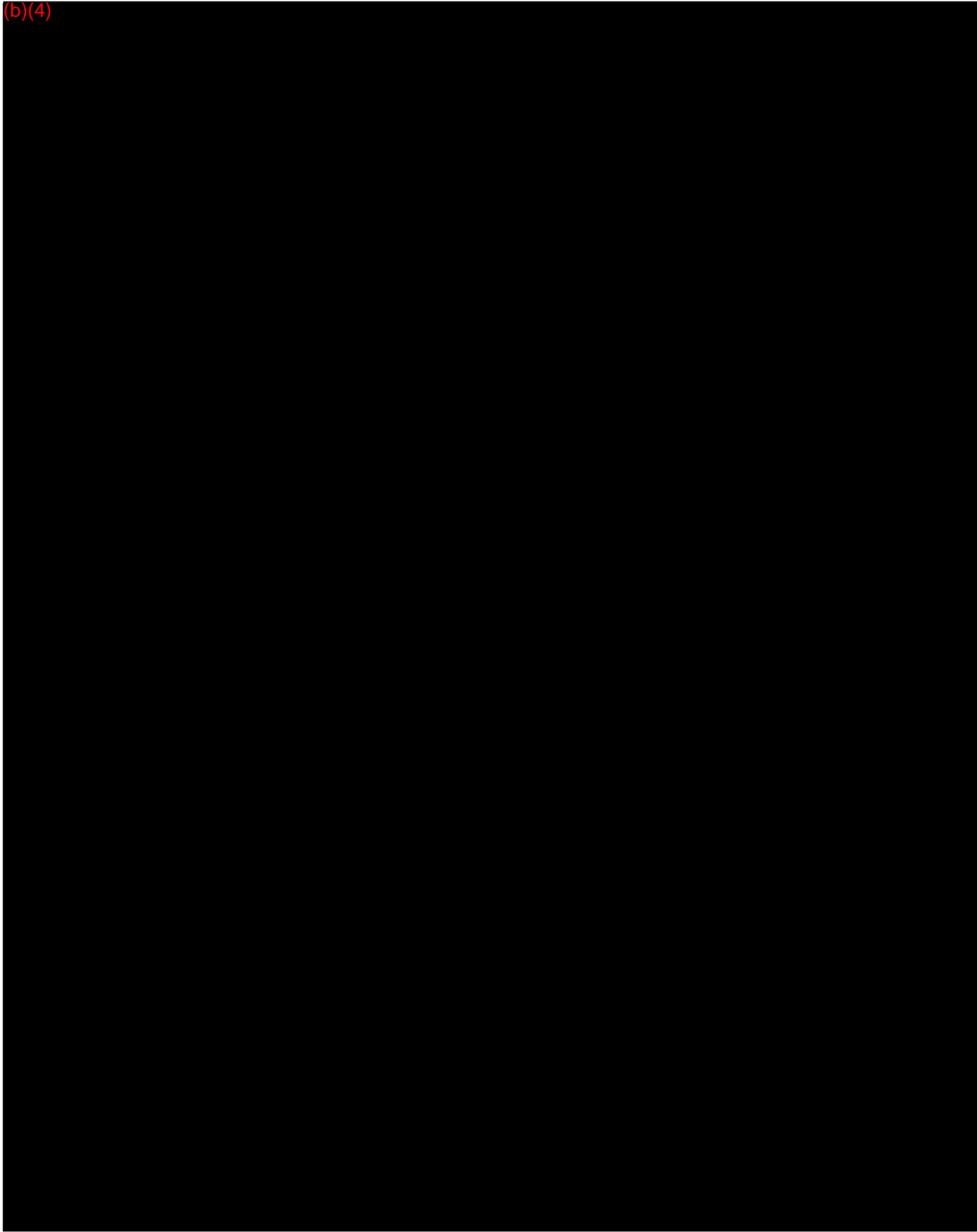
⁶ Please see **Attachment 1** for the complete SE Letter.

⁷ It is unclear from the SE Letter whether FDA considers the break lines between the sentences it requires are themselves part of the required labeling. As a worst case, Synthes has included those line breaks in the proposed labeling presented in this submission.

⁸ The typeface used is Times New Roman, the same typeface as used in this submission. Times New Roman has been found to be the least fatiguing typeface to read. FDA Guidance, "Human Factors Principles for Medical Device Labeling" 1993, p.17.

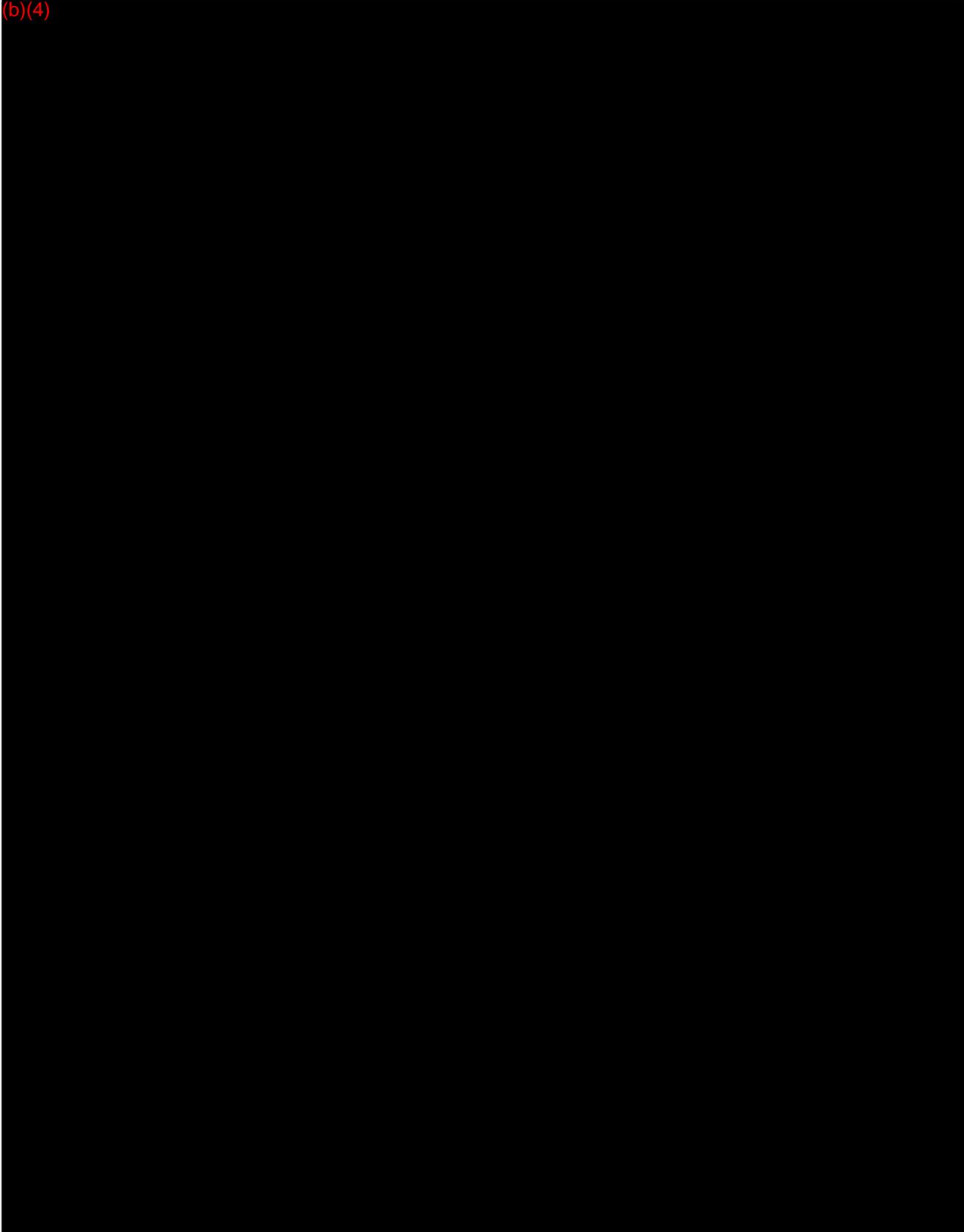


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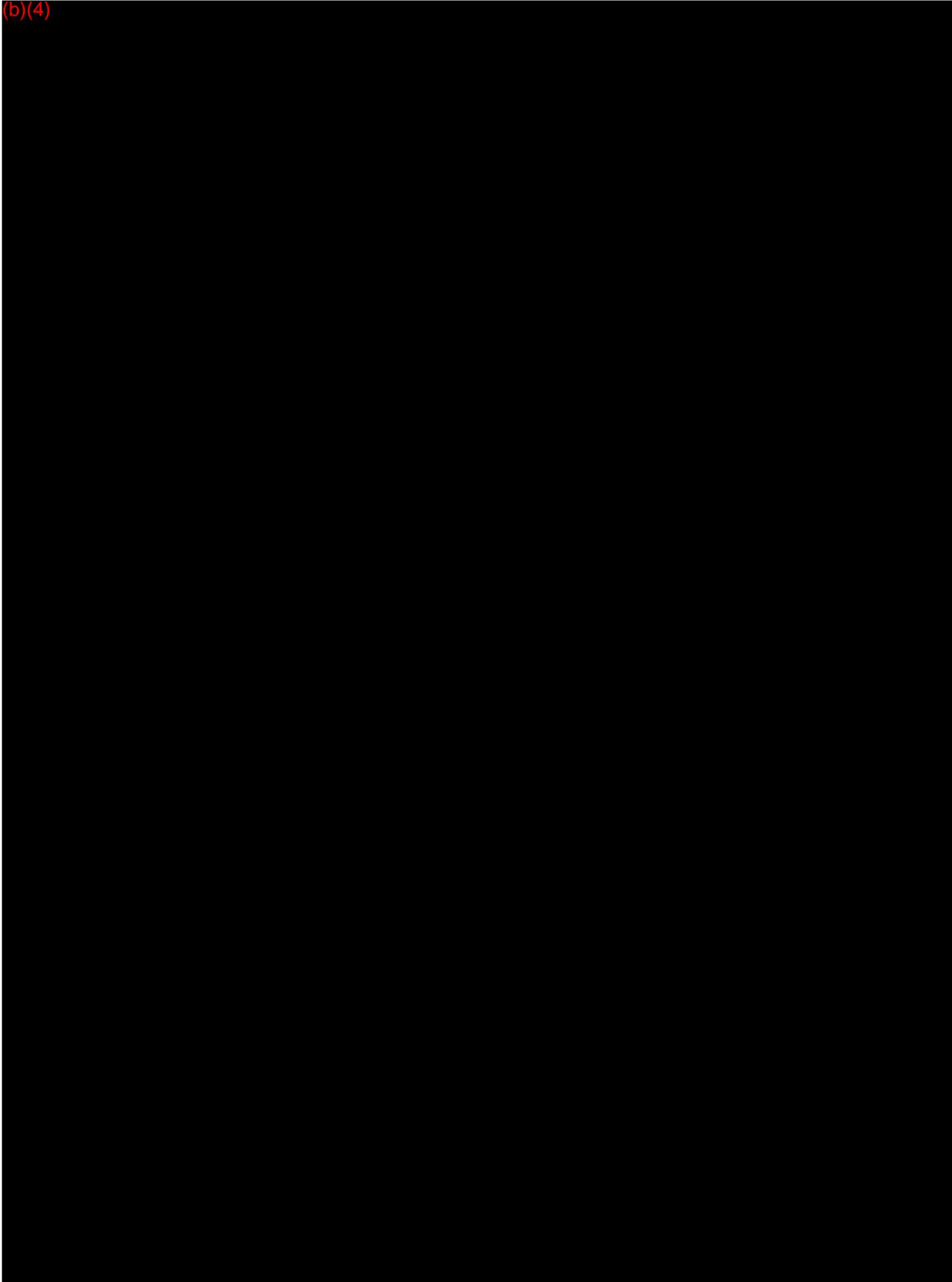


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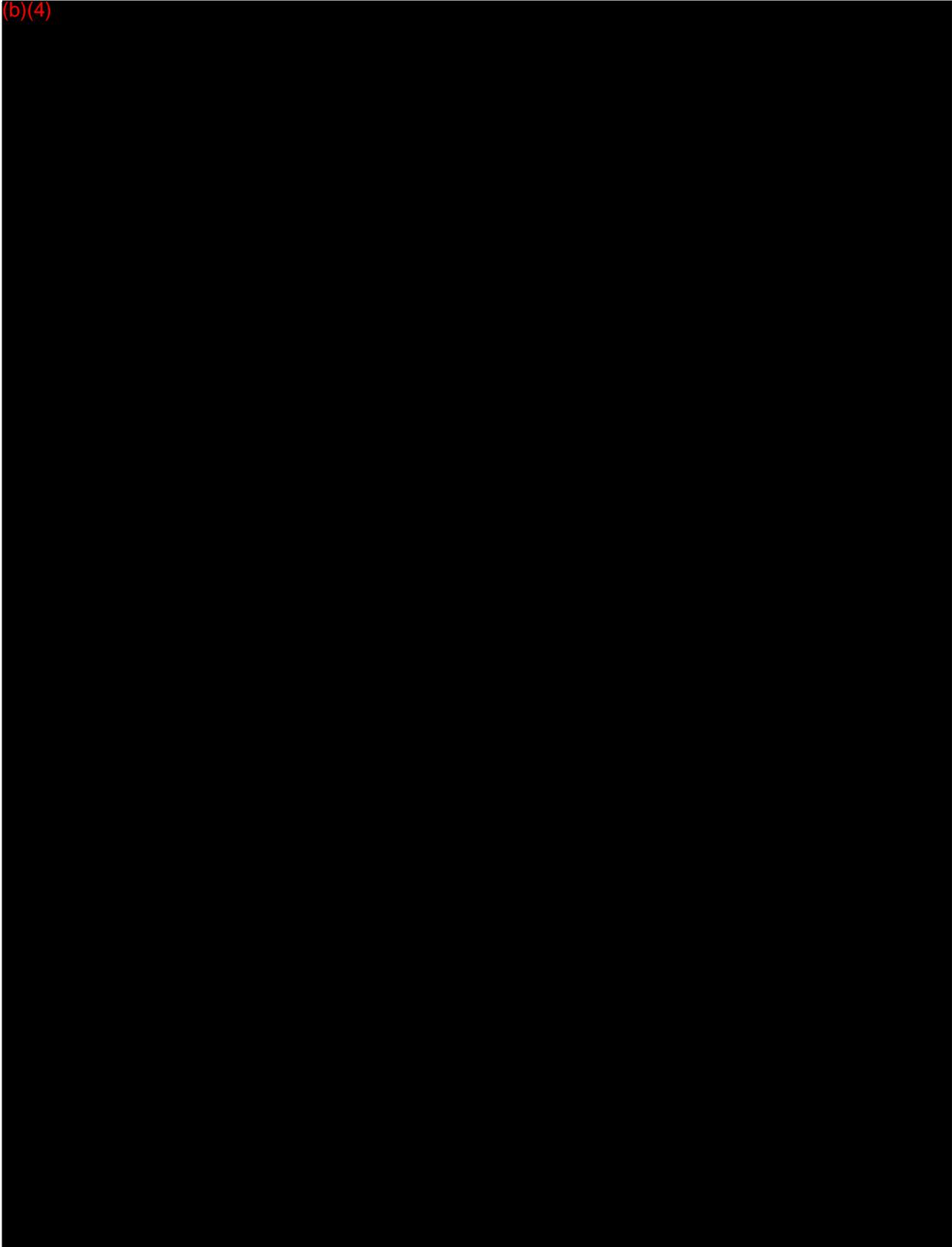


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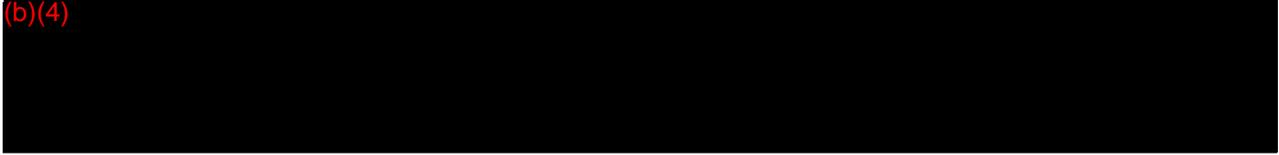


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DEPARTMENT OF HEALTH & HUMAN SERVICES

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.

Page 2 - Mr. Jeffrey L. Dow, JD

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*TM 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*TM 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*TM are intended to be placed into bony voids either before or after final fixation.

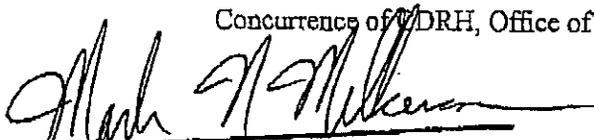
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



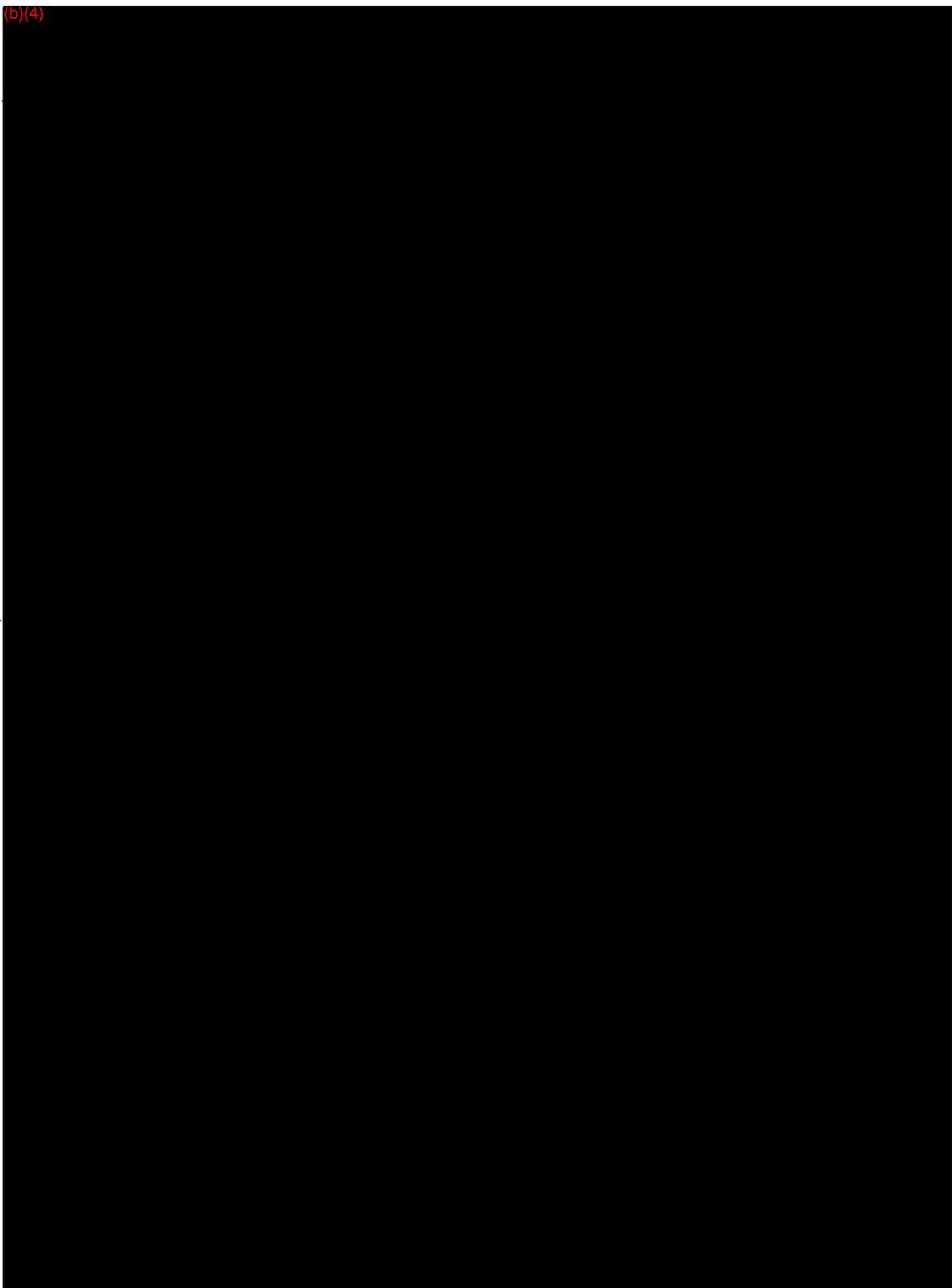
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

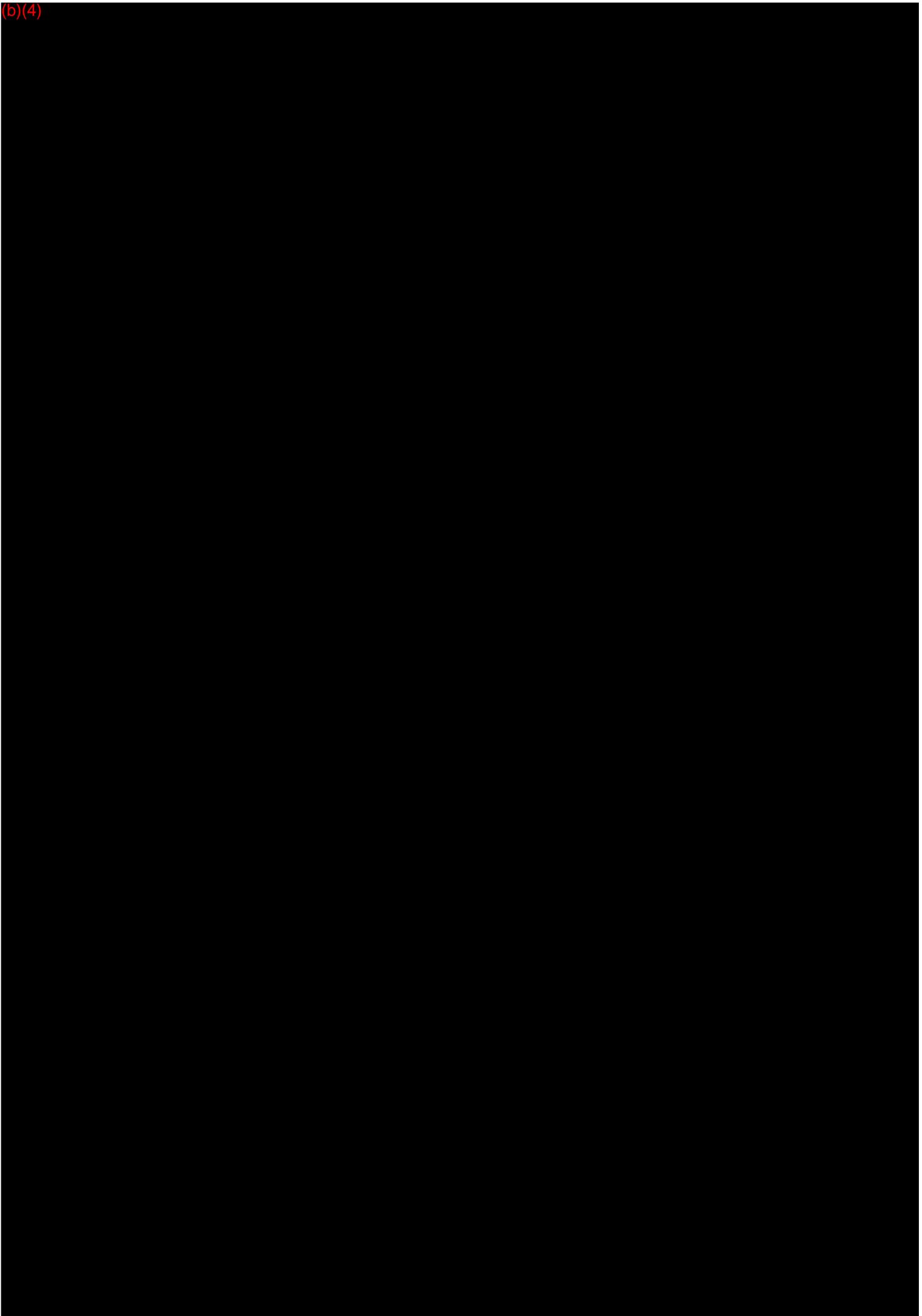
Page 1 of 1

510(k) Number K073303

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P

INDICATIONS

Norian Drillable Bone Void Filler is 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 can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has 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 is intended to be placed into bony voids either before or after final fixation.

CONTRAINDICATIONS

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.

Norian Drillable Bone Void Filler should not be used in the presence of active or suspected infection.

Norian Drillable Bone Void Filler is not for screw augmentation.

Norian Drillable Bone Void Filler is not for use in:

- **Patients with traumatic open injuries that are predisposed to infection**
- **Stress bearing applications**
- **Areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implanted rigid fixation hardware.**
- **Patients with compromised health (e.g. abnormal calcium metabolism, metabolic bone disease, a recent local untreated infection, vascular or severe neurological disease, infection, immunologic deficiencies or systemic disorders) that result in poor wound healing or will result in tissue deterioration over the implant site.**
- **Patients who are skeletally immature**
- **Vertebral compression fractures**
- **Intra-articular space (i.e., material injected into the joint space).**

**IMPORTANT INFORMATION
ON THE
NORIAN DRILLABLETM INJECT**

DESCRIPTION

Norian Drillable Inject is an injectable and biocompatible bone void filler with added reinforcing fibers. Norian Drillable Inject is intended to be placed into bony voids either before or after final fixation. The material can be drilled and tapped, and screws can be placed through it at any time during the setting process. When fully cured, the composition formed closely approximates the mineral phase of bone.

Norian Drillable Inject is provided in a Reactants Pack. The Reactants Pack contains sterile powder (calcium phosphate with absorbable polylactide/glycolide copolymer fibers) and is designed with an injection port for the purpose of adding the sterile solution (dilute sodium phosphate with sodium hyaluronate) to the pouch. The sterile solution is contained in the Solution Syringe, which is packaged separately. The Reactants Pack is designed to be placed in a reusable mixer (Rotary Mixer) where the 2 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 Inject begins to harden after 2 minutes and sets in approximately 10 minutes. Norian Drillable Inject is slowly resorbed and replaced with bone during the healing process.

INDICATIONS

Norian Drillable Inject is 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 Inject can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject is intended to be placed into bony voids either before or after final fixation.

CONTRAINDICATIONS

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.

Norian Drillable Inject is not intended for use in the spine and should not be used in the presence of active or suspected infection.

Norian Drillable Inject is not for screw augmentation.

Norian Drillable Inject is not for use in:

- Patients with traumatic open injuries that are predisposed to infection
- Stress bearing applications
- Areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implanted rigid fixation hardware.
- Patients with compromised health (e.g. abnormal calcium metabolism, metabolic bone disease, a recent local untreated infection, vascular or severe neurological disease, infection, immunologic deficiencies or systemic disorders) that result in poor wound healing or will result in tissue deterioration over the implant site.
- Patients who are skeletally immature

WARNINGS

- Norian Drillable Inject is for single use only, and should not be resterilized.
- Remove excess material in adjacent soft tissue.
- Norian Drillable Inject is provided sterile. If integrity of the package is compromised, the product must be assumed non-sterile and appropriately discarded.
- Norian Drillable Inject should be implanted within 5 minutes after mixing. Discard any unused material.
- The safety and effectiveness of Norian Drillable Inject when used in patients having received or to receive chemotherapy or radiation therapy at or near the implant site are not known.
- The safety and effectiveness of Norian Drillable Inject when combined with Autograft, Allograft, muscle grafts, dura, fascia, abdominal fat, acrylic, silicone, or polymer are not yet established.
- The effect of layering Norian Drillable Inject is not known.
- Do not mix Norian Drillable Inject with any other substance, as this may alter the safety and effectiveness of the material and could prevent the material from setting.
- Highly pressurized application of Norian Drillable Inject into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown.
- Limit manipulation of the surgical site during the setting time, 10 minutes at body temperature (37°C / 98.6°F), to drilling, tapping, or inserting fixation hardware.
- Do not overfill the defect site.
- Do not remove any hardware until after the device has cured for 24 hours.
- Do not use if temperature indicator has been activated (as shown by indicator dot turning black).

PRECAUTIONS

- The medical professional is responsible for using his/her best medical judgment prior to using this or any other medical device. In particular, familiarity with the use of bone void fillers for filling defects in bone, mixing instructions, instrumentation, injection technique, Preparation Time, Implantation Time, Setting Time and Cure Time are required prior to treatment.
- The Norian Drillable Inject Reactants Pack and Rotary Mixer should be equilibrated to 18°-23°C / 64°-73°F prior to mixing.
- If more than one Reactants Pack is required, the total volume (not to exceed 40cc) of Norian Drillable Inject should be implanted within the 2-minute Implantation Time.
- Due to the radiopacity of the material, anomalies may not be detected.
- Norian Drillable Inject attains physiologic pH after components are mixed. In the unlikely event that the seal of the Reactants Pack is breached during mixing, proper eye protection and surgical gloves should be worn when cleaning up the components. Seek medical attention if the components are ingested or inhaled. If skin or eye contact occurs, do the following and seek medical attention if irritation occurs:
 - **Skin exposure:** Wash area with soap and water.
 - **Eye exposure:** Flush thoroughly with running water.
- The effect of Norian Drillable Inject on patients with the following indications or conditions is not known:
 - Individuals who will not or cannot follow a prescribed rehabilitation course such as with alcohol or drug abusers
 - Defects due to congenital malformation or metabolic disease
 - Documented renal disease
 - Pregnancy and/or nursing women
 - Cardiovascular disease precluding elective surgery
 - Osteoporosis
- A successful result is not achieved in every surgical case. If reoperation is required, the device should be removed and the surrounding bone should be re-evaluated to make sure it is still viable.
- Unused Norian Drillable Inject should be discarded. Before disposal of a Reactants Pack, mix according to the Directions for Use to render the contents pH neutral.
- The recommended application of Norian Drillable Inject is to fill bone defects that have been stabilized using standard orthopaedic reduction techniques and fixation protocol, i.e., external fixation pins, K-wires, plates, screws, etc.
- If the Preparation Time (5 minutes from end of mixing process) elapses, the remaining Norian Drillable Inject that has not been implanted must be discarded and a new Reactants Pack mixed.
- Because Norian Drillable Inject must be placed in the void within 5 minutes from the end of mixing, the surgeon should develop a preoperative plan. This requires understanding the method, sequence, and estimated volume of Norian Drillable Inject needed to fill the void. The plan should be confirmed intraoperatively by direct visualization or under real-time image intensification.
- Excess fluids could result in device malfunction (e.g. washing away prior to setting).
- To avoid inadvertent delivery of Norian Drillable Inject (i.e. into the intra-articular space), injection of the material should be performed under direct visualization or under real-time image intensification.
- The long term effects of extraosseous Norian Drillable Inject or intra-articular Norian Drillable Inject (material injected into the joint space) are unknown. Irritation or inflammation may be possible complications associated with large extraosseous deposits of Norian Drillable Inject. If the material is implanted into the joint or soft tissue, care should be taken to remove the excess material by irrigating it away from the site.
- Arthritis may be a possible complication of intra-articular Norian Drillable Inject.

- Fractures with intra-articular involvement should be properly reduced according to ORIF technique prior to injecting Norian Drillable Inject. Extra care must be taken to ensure Norian Drillable Inject has not entered the joint space when the bone void being filled is adjacent to the articular surface.
- Fractured articular surfaces where Norian Drillable Inject can communicate with the joint should be sealed prior to injection of Norian Drillable Inject. This can be accomplished by utilizing a sequential injection technique wherein Norian Drillable Inject is first implanted in the subchondral area without application of pressure on the material. After allowing the material to partially set, additional Norian Drillable Inject can be implanted to fill the remaining bone void.
- Over-pressurizing the device may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues.
- Over-pressurizing the defect site may lead to fat embolization or embolization of the device material into the bloodstream.
- Norian Drillable Inject should not be used as a screw anchor. Screws placed through the material should be supported by bone on both sides of the material, according to proper orthopedic reduction technique.
- Placing guide wires (e.g. K-wires) through Norian Drillable Inject may cause the material to fracture. If guide wires are to be used, it is recommended that the guide wire is inserted into Norian Drillable Inject during the 2-minute implantation time or the 10-minute set time. Placing guide wires through the material after the 10-minute set time has elapsed is not recommended. Monitor the K-wire position when over drilling to ensure the K-wire does not advance with the drill.
- The use of self drilling screws is not recommended with Norian Drillable Inject. If self drilling screws are to be used, it is recommended that the material is pre-drilled to the root diameter of the screw.
- As with most materials, placing screws near the edge of the implanted Norian Drillable Inject may cause the Bone Void Filler to fracture.
- The use of cannulated screws with thread diameters greater than 5.0mm over a guide wire is not recommended.

POSSIBLE COMPLICATIONS

As with any surgical procedure, certain complications may be associated with treatment such as pain, hematoma, seromas, tenderness, redness, edema, extrusion, device fracture, migration, loss of contour, drainage, and infection. The occurrence of any of these complications may require reoperation and/or removal of the device.

HOW DEVICE IS SUPPLIED

Norian Drillable Inject is packaged in a Reactants Pack, which includes the compartment for the Powder with an integral injection port and Delivery Syringe (see Figure 1). The Solution Syringe containing the mixing solution is separately packaged along with the Reactants Pack.

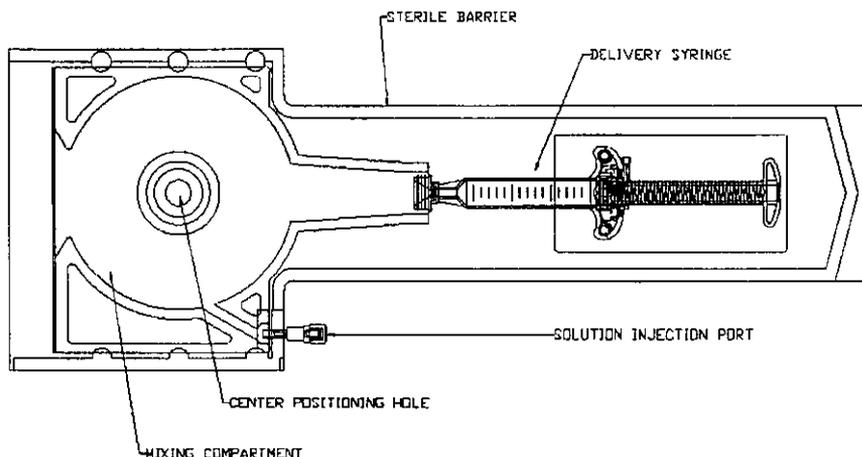
STERILITY

The Norian Drillable Inject Reactants Pack is supplied **sterile** and **non-pyrogenic**. The components of Norian Drillable Inject are sterilized separately by different methods including: gamma irradiation, ethylene oxide, and aseptic filling. **Do not resterilize**. This product is intended for **Single Use Only**. Sterile product packaging should be inspected and if compromised, the product must be assumed non-sterile and appropriately discarded. Do not implant expired product.

STORAGE

Store at room temperature, 5°-25°C / 41°-77°F. Avoid excessive heat or humidity. Do not use if temperature indicator has been activated (as shown by indicator dot turning black).

FIGURE 1: Norian Drillable Inject Reactants Pack for Rotary Mixer



DIRECTIONS FOR USE

PRECAUTION: The Norian Drillable Inject Reactants Pack and Rotary Mixer should be equilibrated to 18°-23°C / 64°-73°F prior to mixing.

Step 1: Mixing Outside the Sterile Field

Rotary Mixer - Power Operation

1. Unwrap the power cord and connect to an appropriate hospital grade outlet. Once connected, the Standby indicator will illuminate indicating that the unit is ready for operation.
2. Open the lid by depressing thumb latch on right corner of lid surface.
3. Position the reactants pack on the mixer by aligning the arrows on the reactants pack and mixer.
4. Press the pack over the center post of the mixer.
5. Inject the solution into the Reactants Pack using aseptic technique.

Note: Once the solution has been injected into the Reactants Pack, the remaining steps must be completed immediately.

6. Remove the pouch clip from the Reactants Pack and unfold with the Delivery Syringe to the right.
7. Close the lid and secure by depressing the thumb latch.
8. Depress the Start button. A single brief beep will be heard, the Standby indicator will turn off and the Mixing indicator will illuminate.
9. After 70 revolutions, the mixing cycle is complete. An extended beep will be heard and the "Mix Complete" indicator will slowly flash. The Rotary Mixer will continue to beep every five seconds until the lid is opened.

CAUTION: If the Rotary Mixer fails to complete the mixing cycle, or the lid is opened before the cycle is complete, an audible alarm will sound and all function indicators will flash. Using a new reactants pack, return to step 2 or mix using Manual Operation (see below) with a new Reactants Pack.

Manual Operation

1. Follow steps 2 - 6 above.
2. Lift up on the manual handle and rotate the top disk 70 revolutions clockwise.

Instructions for Transfer - Powered and Manual Operation

1. Open the lid and lift the mixed Reactants Pack from the center post.
2. Guide the pack and turn the knob counterclockwise to feed the Reactants Pack into the transfer rollers. The material will be expelled from the mixing chamber into the Delivery Syringe.
3. Once the material is completely transferred, turn the transfer knob clockwise to remove the Reactants Pack.
4. Using aseptic technique, grasp the sides of the outer pouch and peel back at the Delivery Syringe to separate outer packaging and expose it.
5. Present the Delivery Syringe to the Scrub Nurse.

Step 2: Instructions for Use within the Sterile Field

1. Allow the Scrub Nurse to grasp the Delivery Syringe as the Circulating Nurse peels the outer pouch open.
2. Remove the device from Reactants Pack by twisting it counterclockwise approximately 1/4 turn until it releases.
3. Attach a Delivery Needle and remove the clip from the syringe plunger. The material is now ready for delivery.

Step 3: Surgical Technique

1. **Prepare Implant Site:** Remove blood clots and tissue debris; lavage and/or suction instruments may be used. Control active bleeding. Prepare the void by compacting the cancellous bone with a curette elevator or similar instrument.

Note: If bone wax or gelfoam is used, it should be removed prior to implanting Norian Drillable Inject.

2. **Mix:** Use the Rotary Mixer to mix the Reactants Pack.

Note: The 5-minute Preparation Time and the 2-minute Implantation Time described below are not sequential. The 2-minute Implantation Time begins when material injection is initiated, which must occur within the 5-minute Preparation Time.

3. **Preparation Time** (5 minutes at room temperature, 18°-23°C / 64°-73°F):

- Remove the Reactants Pack from the Rotary Mixer and transfer the Delivery Syringe to the sterile field. Attach the Delivery Needle. Norian Drillable Inject remains injectable for 5 minutes.
- Injection of Norian Drillable Inject should be performed under direct visualization or under real-time image intensification. If obstruction of the needle occurs, the needle should be discarded and replaced with a new needle.
- Insert the needle into the operative site and begin to deliver the Norian Drillable Inject.

PRECAUTION: If the Preparation Time (5 minutes from end of mixing process) elapses, the remaining Norian Drillable Inject that has not been implanted must be discarded and a new Reactants Pack mixed.

4. **Implantation Time** (2 minutes at body temperature, 37°C / 98.6°F):

- Norian Drillable Inject is intended to be placed into bony voids either before or after final fixation.
- At body temperature (37°C / 98.6°F), Norian Drillable Inject begins to set approximately 2 minutes following implantation and may be considered set 10 minutes after implantation is completed.

PRECAUTION: If more than one Reactants Pack is required, the total volume (not to exceed 40cc) of Norian Drillable Inject should be implanted within the 2-minute Implantation Time.

5. **Setting Time** (10 minutes at body temperature, 37°C / 98.6°F):

- The material can be drilled and tapped, and screws can be placed through it at any time after injection. When placing screws into Norian Drillable Inject, it is recommended that a hole be pre-drilled to the root diameter of the screw.
- Proceed slowly and irrigate while drilling through Norian Drillable Inject. Clear excess material from flutes of drill. After drilling or tapping through material, lightly irrigate to remove excess debris.

PRECAUTION: Placing guide wires (e.g. K-wires) through fully set Norian Drillable Inject may cause the material to fracture. If guide wires are to be used, it is recommended that the guide wire is inserted into Norian Drillable Inject during the 2-minute implantation time or the 10-minute set time. Placing guide wires through the material after the 10-minute set time has elapsed is not recommended.

PRECAUTION: Do not place self-drilling screws through the set material without pre-drilling to the root diameter of the screw.

PRECAUTION: Norian Drillable Inject should not be used as a screw anchor. Screws placed through the material should be supported by bone on both sides of the material, according to proper orthopedic reduction technique.

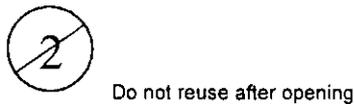
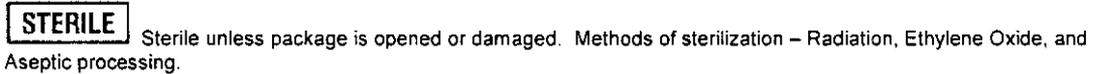
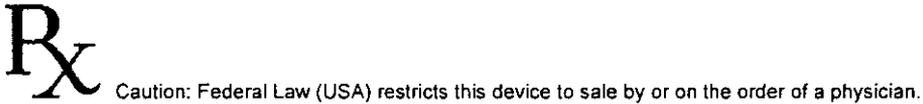
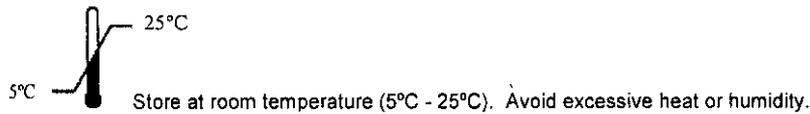
- Release the tourniquet if used and gently irrigate with warm saline to return the operative site to core body temperature.
- At body temperature (37°C / 98.6°F), Norian Drillable Inject may be considered set 10 minutes after implantation is completed.

Note: If the material has not set in 30 minutes, remove it and start over with a new Reactants Pack.

6. **Discard any unused material**
7. **Cure Time** (24 hours at body temperature, 37°C / 98.6°F): Norian Drillable Inject reaches its ultimate compressive strength by 24 hours.

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN**

SYMBOLS USED ON LABELING



Distributed By:
SYNTHES (USA)
1101 Synthes Avenue
Monument, CO 80132
U.S.A.

Norian Drillable is a trademark of Synthes, Inc or its affiliates.

Printed in the U.S.A.

**IMPORTANT INFORMATION
ON THE
NORIAN DRILLABLE™ FAST SET PUTTY™**

DESCRIPTION

Norian Drillable Fast Set Putty is a moldable and biocompatible bone void filler with added reinforcing fibers. Norian Drillable Fast Set Putty is intended to be placed into bony voids either before or after final fixation. The material can be drilled and tapped, and screws can be placed through it at any time during the setting process. When fully cured, the composition formed closely approximates the mineral phase of bone.

Norian Drillable Fast Set Putty is provided in two containers; the mixing cup holds sterile powder (calcium phosphate with absorbable polylactide/glycolide co-polymer fibers) and the solution syringe holds sterile solution (dilute sodium phosphate with sodium hyaluronate). When the powder and solution are mixed together with the provided cup and spatula, the resultant putty material is suitable for filling bony voids or gaps of the skeleton. 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, depending on volume. Norian Drillable Fast Set Putty is slowly resorbed and replaced with bone during the healing process.

INDICATIONS

Norian Drillable Fast Set Putty is 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 Fast Set Putty can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Fast Set Putty is intended to be placed into bony voids either before or after final fixation.

CONTRAINDICATIONS

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.

Norian Drillable Fast Set Putty is not intended for use in the spine and should not be used in the presence of active or suspected infection.

Norian Drillable Fast Set Putty is not for screw augmentation.

Norian Drillable Fast Set Putty is not for use in:

- **Patients with traumatic open injuries that are predisposed to infection**
- **Stress bearing applications**
- **Areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implanted rigid fixation hardware.**
- **Patients with compromised health (e.g. abnormal calcium metabolism, metabolic bone disease, a recent local untreated infection, vascular or severe neurological disease, infection, immunologic deficiencies or systemic disorders) that result in poor wound healing or will result in tissue deterioration over the implant site.**
- **Patients who are skeletally immature**
- **Vertebral compression fractures**
- **Intra-articular space (i.e., material placed into the joint space).**

WARNINGS

- Mix materials into a homogeneous putty prior to implantation.
- Norian Drillable Fast Set Putty is for single use only, and should not be resterilized.
- Remove excess material in adjacent soft tissue.
- Norian Drillable Fast Set Putty is provided sterile. If integrity of the package is compromised, the product must be assumed non-sterile and appropriately discarded.
- Norian Drillable Fast Set Putty should be implanted within 2 minutes after mixing. Discard any unused material.
- The safety and effectiveness of Norian Drillable Fast Set Putty when used in patients having received or to receive chemotherapy or radiation therapy at or near the implant site are not known.
- The safety and effectiveness of Norian Drillable Fast Set Putty when combined with Autograft, Allograft, muscle grafts, dura, fascia, abdominal fat, acrylic, silicone, or polymer are not yet established.
- The effect of layering Norian Drillable Fast Set Putty is not known.
- Do not mix Norian Drillable Fast Set Putty with any other substance, as this may alter the safety and effectiveness of the material and could prevent the material from setting.
- Highly pressurized application of Norian Drillable Fast Set Putty into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown.
- Limit manipulation of the surgical site during the setting time, 3-6 minutes at body temperature (37°C / 98.6°F), to drilling, tapping, or inserting fixation hardware.
- Do not overfill the defect site.
- Do not remove any hardware until after the device has cured for 24 hours.
- Do not use if temperature indicator has been activated (as shown by indicator dot turning black).

PRECAUTIONS

- The medical professional is responsible for using his/her best medical judgment prior to using this or any other medical device. In particular, familiarity with the use of bone void fillers for filling defects in bone, mixing instructions, instrumentation, injection technique, Preparation Time, Implantation Time, Setting Time and Cure Time are required prior to treatment.
- The Norian Drillable Fast Set Putty package should be equilibrated to 18°-23°C / 64°-73°F prior to mixing.
- If more than one package is required, the total volume (not to exceed 40cc) of Norian Drillable Fast Set Putty should be implanted within the 2-minute Implantation Time.
- Due to the radiopacity of the material, anomalies may not be detected.
- Norian Drillable Fast Set Putty attains physiologic pH after components are mixed. Proper eye protection and surgical gloves should be worn when cleaning up the components. Seek medical attention if the components are ingested or inhaled. If skin or eye contact occurs, do the following and seek medical attention if irritation occurs:
 - **Skin exposure:** Wash area with soap and water.
 - **Eye exposure:** Flush thoroughly with running water.
- The effect of Norian Drillable Fast Set Putty on patients with the following indications or conditions is not known:
 - Individuals who will not or cannot follow a prescribed rehabilitation course such as with alcohol or drug abusers
 - Defects due to congenital malformation or metabolic disease
 - Documented renal disease
 - Pregnancy and/or nursing women
 - Cardiovascular disease precluding elective surgery
 - Osteoporosis
- A successful result is not achieved in every surgical case. If reoperation is required, the device should be removed and the surrounding bone should be re-evaluated to make sure it is still viable.
- Unused Norian Drillable Fast Set Putty should be discarded. Before disposal, mix according to the Directions for Use to render the contents pH neutral.
- The recommended application of Norian Drillable Fast Set Putty is to fill bone defects that have been stabilized using standard orthopaedic reduction techniques and fixation protocol, i.e., external fixation pins, K-wires, plates, screws, etc.
- If the Preparation Time (2 minutes from end of mixing process) elapses, the remaining Norian Drillable Fast Set Putty that has not been implanted must be discarded and a new package mixed.
- Because Norian Drillable Fast Set Putty must be placed in the void within 2 minutes from the end of mixing, the surgeon should develop a preoperative plan. This requires understanding the method, sequence, and estimated volume of Norian Drillable Fast Set Putty needed to fill the void. The plan should be confirmed intraoperatively by direct visualization or under real-time image intensification.
- Excess fluids could result in device malfunction (e.g. washing away prior to setting)
- To avoid inadvertent delivery of Norian Drillable Fast Set Putty (i.e. into the intra-articular space), placement of the material should be performed under direct visualization or under real-time image intensification.
- The long term effects of extraosseous Norian Drillable Fast Set Putty or intra-articular Norian Drillable Fast Set Putty (material injected into the joint space) are unknown. Irritation or inflammation may be possible complications associated with large extraosseous deposits of Norian Drillable Fast Set Putty. If the material is implanted into the joint or soft tissue, care should be taken to remove the excess material by irrigating it away from the site.
- Arthritis may be a possible complication of intra-articular Norian Drillable Fast Set Putty.

- Fractures with intra-articular involvement should be properly reduced according to ORIF technique prior to implanting Norian Drillable Fast Set Putty. Extra care must be taken to ensure Norian Drillable Fast Set Putty has not entered the joint space when the bone void being filled is adjacent to the articular surface.
- Over-pressurizing the device may lead to extrusion of the device beyond the site of its intended application and damage to the surrounding tissues.
- Over-pressurizing the defect site may lead to fat embolization or embolization of the device material into the bloodstream.
- Norian Drillable Fast Set Putty should not be used as a screw anchor. Screws placed through the material should be supported by bone on both sides of the material, according to proper orthopedic reduction technique.
- Placing guide wires (e.g. K-wires) through Norian Drillable Fast Set Putty may cause the material to fracture. If guide wires are to be used, it is recommended that the guide wire is inserted into Norian Drillable Fast Set Putty during the 2-minute implantation time or the 3-6 minute set time. Placing guide wires through the material after the 3-6 minute set time has elapsed is not recommended. Monitor the K-wire position when over drilling to ensure the K-wire does not advance with the drill.
- The use of self drilling screws is not recommended with Norian Drillable Fast Set Putty. If self drilling screws are to be used, it is recommended that the material is pre-drilled to the root diameter of the screw.
- As with most materials, placing screws near the edge of the implanted Norian Drillable Fast Set Putty may cause the Norian Drillable Fast Set Putty to fracture.
- The use of cannulated screws with thread diameters greater than 5.0 mm over a guide wire is not recommended.

POSSIBLE COMPLICATIONS

As with any surgical procedure, certain complications may be associated with treatment such as pain, hematoma, seromas, tenderness, redness, edema, extrusion, device fracture, migration, loss of contour, drainage, and infection. The occurrence of any of these complications may require reoperation and/or removal of the device.

HOW DEVICE IS SUPPLIED

Norian Drillable Fast Set Putty is provided in two containers; the mixing cup holds sterile powder and the solution syringe holds sterile solution.

STERILITY

Norian Drillable Fast Set Putty is supplied **sterile** and **non-pyrogenic**. The components of Norian Drillable Fast Set Putty are sterilized separately by different methods including: gamma irradiation, ethylene oxide, and aseptic filling. **Do not resterilize**. This product is intended for **Single Use Only**. Sterile product packaging should be inspected and if compromised, the product must be assumed non-sterile and appropriately discarded. Do not implant expired product.

STORAGE

Store at room temperature, 5°-25°C / 41°-77°F. Avoid excessive heat or humidity. Do not use if temperature indicator has been activated (as shown by indicator dot turning black).

DIRECTIONS FOR USE

PRECAUTION: The Norian Drillable Fast Set Putty package should be equilibrated to 18°-23°C / 64°-73°F prior to mixing.

1. **Prepare Implant Site:**

- Remove blood clots and tissue debris; lavage and/or suction instruments may be used. Control active bleeding.
- Prepare the void by compacting the cancellous bone with a curette elevator or similar instrument.

Note: If bone wax or gelfoam is used, it should be removed prior to implanting Norian Drillable Fast Set Putty.

2. **Mix Components:**

- Transfer the tray containing the mixing cup and the tray containing the solution syringe to sterile field using aseptic technique.

Important: The tray containing product can not be stored once the outer pouch has been opened.

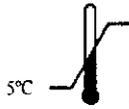
- When the site is ready for implantation, prepare materials for mixing. Remove the cup from the tray, tap the cup on a hard surface and slowly peel back the lid to expose the powder. Take care not to spill any powder.
- Remove the syringe from the tray and deliver the liquid onto the powder, ensuring that all liquid is removed from the syringe.

- Using the spatula provided, mix the powder and liquid components together for 45-90 seconds, depending on volume. Use a sweeping motion along the side of the cup to incorporate all powder into the mix. Ensure that the components are fully integrated to produce homogenous putty.
3. **Implantation Time** (2 minutes at body temperature, 37°C / 98.6°F):
- Immediately apply the putty to the defect site using the spatula or by hand. Contour the putty manually, using a wet gloved finger or surgical instrument. Complete all contouring within two minutes of implantation.
- PRECAUTION:** The size or nature of the void or defect may require more than one package. If so, the total volume of Norian Drillable Fast Set Putty implanted in that void or defect must be implanted within the 2 minute period commencing at the moment when the Norian Drillable Fast Set Putty from the first package begins to be implanted. Disturbing the first Norian Drillable Fast Set Putty implanted after that 2 minute period may damage the construct.
- Norian Drillable Fast Set Putty is intended to be placed into bony voids either before or after final fixation.
4. **Setting Time** (3-6 minutes at body temperature, 37°C / 98.6°F):
- The material can be drilled and tapped, and screws can be placed through it at any time after implantation. When placing screws into Norian Drillable Fast Set Putty, it is recommended that a hole be pre-drilled to the root diameter of the screw.
 - Proceed slowly and irrigate while drilling through Norian Drillable Fast Set Putty. Clear excess material from flutes of drill. After drilling or tapping through material, lightly irrigate to remove excess debris.
- PRECAUTION:** Placing guide wires (e.g. K-wires) through fully set Norian Drillable Fast Set Putty may cause the material to fracture. If guide wires are to be used, it is recommended that the guide wire is inserted into Norian Drillable Fast Set Putty during the 2-minute implantation time or the 3-6 minute set time. Placing guide wires through the material after the 3-6 minute set time has elapsed is not recommended.
- PRECAUTION:** Do not place self-drilling screws through the set material without pre-drilling to the root diameter of the screw.
- PRECAUTION:** Norian Drillable Fast Set Putty should not be used as a screw anchor. Screws placed through the material should be supported by bone on both sides of the material, according to proper orthopedic reduction technique.
- Release the tourniquet, if used, and gently irrigate with warm saline to return the operative site to core body temperature (37°C / 98.6°F).
 - The putty will set within 3 to 6 minutes at normal body temperature, 37°C. Drip irrigate with warm water during the 3 to 6 minute setting period. Once the putty begins to harden, it must be left undisturbed to avoid cracking and/or crumbling.
5. **Discard any unused material**
6. **Cure Time** (24 hours at body temperature, 37°C / 98.6°F): Norian Drillable Fast Set Putty reaches its ultimate compressive strength by 24 hours

**CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE
TO SALE BY OR ON THE ORDER OF A PHYSICIAN**

SYMBOLS USED ON LABELING

25°C



Store at room temperature (5°C - 25°C). Avoid excessive heat or humidity.



See instructions for use.



Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.



Sterile unless package is opened or damaged. Methods of sterilization – Radiation, Ethylene Oxide, and Aseptic processing.



Do not reuse after opening

Distributed By:

SYNTHES (USA)
1101 Synthes Avenue
Monument, CO 80132
U.S.A.

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Printed in the U.S.A.

Norian Drillable Inject
~~Rotary Pouch~~

Principal carton label

REF SRS-1000-FRI LOT TEST Qty. 1
Norian Drillable™
10 cc

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.

2012-08

STERILE



Material:
Ca5 (PO4)3OH

5°C 25°C

CE 0123



REF SRS-1000-FRI

Norian Drillable™
10 cc

Back side label on carton

EN Norian Drillable™, 10 cc
DE Norian Drillable™, 10 cc
ES Norian Drillable™, 10 cc
FR Norian Drillable™, 10 cc
IT Norian Drillable™, 10 cc
PT Norian Drillable™, 10 cc

Manufacturer:
Synthes GmbH
Eimattstrasse 3
4438 Oberdorf
Switzerland

90026297, GP2843
Contents sterile unless inner package is open or damaged.

Product label on left side of carton

REF SRS-1000-FRI

Norian Drillable™
10 cc

Product and barcode label on-right side of carton



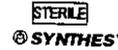
REF SRS-1000-FRI

LOT TEST

Norian Drillable™
10 cc



Material:
Ca5 (PO4)3OH



Patient label strip placed into carton

REF SRS-1000-FRI
Norian Drillable™
10 cc

Material:
Ca5 (PO4)3OH

LOT TEST



SYNTHES

REF SRS-1000-FRI
Norian Drillable™
10 cc

Material:
Ca5 (PO4)3OH

LOT TEST



SYNTHES

REF SRS-1000-FRI
Norian Drillable™
10 cc

Material:
Ca5 (PO4)3OH

LOT TEST



SYNTHES

REF SRS-1000-FRI
Norian Drillable™
10 cc

Material:
Ca5 (PO4)3OH

LOT TEST



SYNTHES

Fast Set Putty

Principal carton label

REF SRS-1000-FRP LOT TEST Qty. 1

Norian Drillable™
Fast Set Putty™, 10 cc

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.



STERILE



Material:
Ca5 (PO4)3OH



REF SRS-1000-FRP

Norian Drillable™
Fast Set Putty™, 10 cc

Back side label on carton

- EN Norian Drillable™ Fast Set Putty™, 10 cc
- DE Norian Drillable™ Fast Set Putty™, 10 cc
- ES Norian Drillable™ Fast Set Putty™, 10 cc
- FR Norian Drillable™ Fast Set Putty™, 10 cc
- IT Norian Drillable™ Fast Set Putty™, 10 cc
- PT Norian Drillable™ Fast Set Putty™, 10 cc

Manufacturer:
Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland

Contents sterile unless inner package is open or damaged.

Product label on left side of carton

REF SRS-1000-FRP

Norian Drillable™
Fast Set Putty™, 10 cc

Product and barcode-label-on-right - side of carton



SRS-1000-FRP
TEST
Norian Drillable™
Fast Set Putty™, 10 cc
Material: CaS (PO4)3OH
STERILE
SYNTHES'

Patient label strip placed into carton

SRS-1000-FRP
Norian Drillable™
Fast Set Putty™, 10 cc
Material: CaS (PO4)3OH
TEST
2010-08
SYNTHES'

SRS-1000-FRP
Norian Drillable™
Fast Set Putty™, 10 cc
Material: CaS (PO4)3OH
TEST
2010-08
SYNTHES'

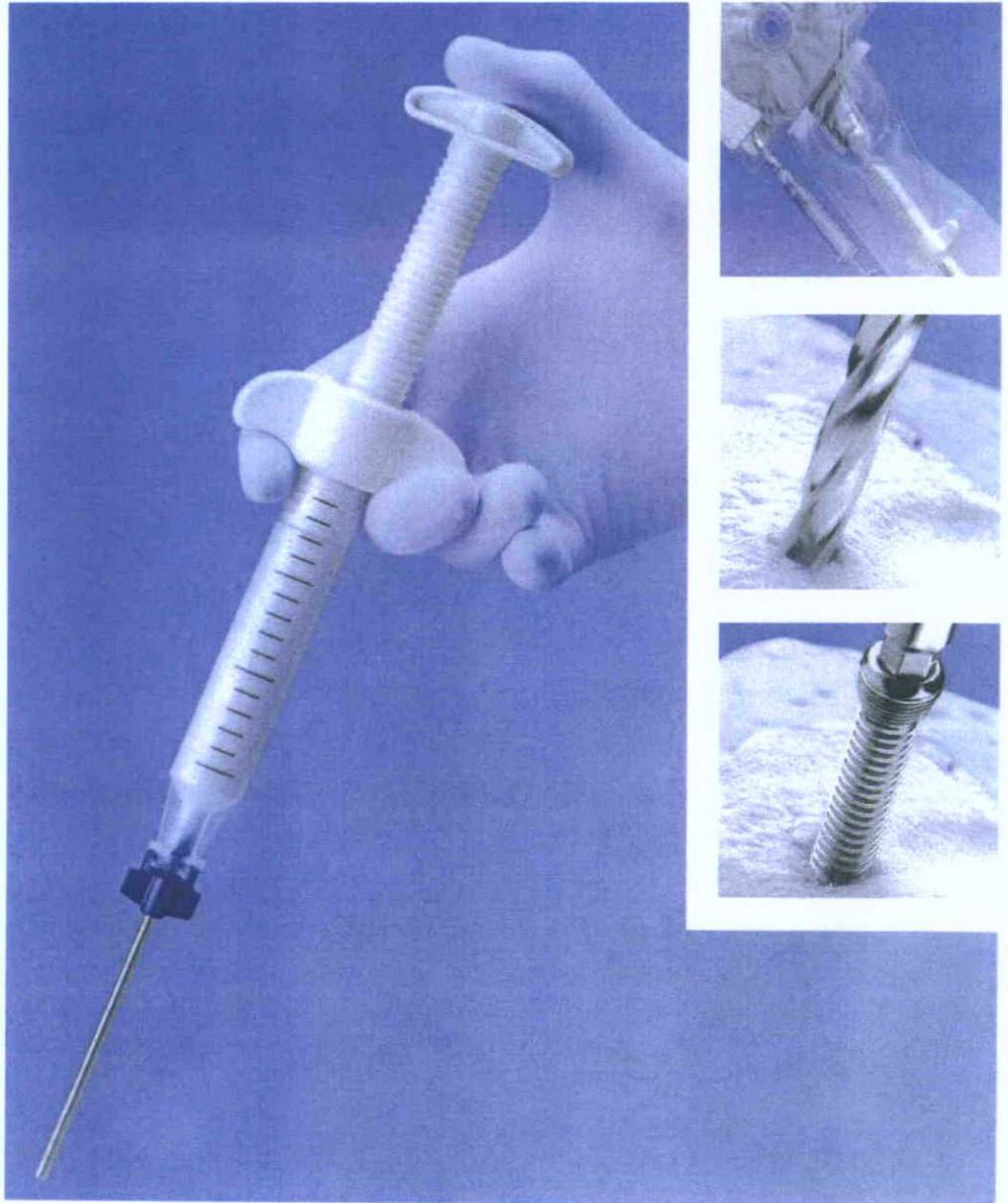
SRS-1000-FRP
Norian Drillable™
Fast Set Putty™, 10 cc
Material: CaS (PO4)3OH
TEST
2010-08
SYNTHES'

SRS-1000-FRP
Norian Drillable™
Fast Set Putty™, 10 cc
Material: CaS (PO4)3OH
TEST
2010-08
SYNTHES'

Norian Drillable Inject. Calcium phosphate bone void filler with reinforcing fibers.

Draft 9/8/10—For Internal Use Only—Not For Distribution

Technique Guide



 **SYNTHES**[®] Instruments and implants
approved by the AO Foundation

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 Image intensifier control

Synthes

100

39

Norian Drillable Inject. The injectable bone void filler for drilling.

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Overview

Norian Drillable Inject is an injectable, biocompatible calcium phosphate bone void filler. Due to its unique material composition it can be drilled, 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.

Key components:

- Calcium phosphate powder
- Bioresorbable fibers
- Liquid component

Calcium phosphate powder



Calcium phosphate has been widely used in clinical applications for decades. There are many publications¹ and clinical cases available which demonstrate its safety and effectiveness to address bone regeneration.

Bioresorbable fibers

+



The bioresorbable fibers are uniformly distributed within the material and provide an increase in toughness and allow the material to be drilled and tapped.

Liquid component

+



The liquid component is a pH-neutral solution to increase viscosity which leads to improved mixing and flow properties.

¹ Examples:

Cassidy C, Jupiter JB, Cohen M, Delli-Santi M, Fennell C, Leinberry C, Husband J, Ladd A, Seitz WR, Constanz B. Norian SRS cement compared with conventional fixation in distal radial fractures. A randomized study. 31: J Bone Joint Surg Am. 2003 Nov; 85- A(11): 2127-37.

Lobenhoffer P, Gerich T, Witte F, Tschern H. Use of an injectable calcium phosphate bone cement in the treatment of tibial plateau fractures: a prospective study of twenty-six cases with twenty-month mean follow-up¹). It's also missing the year of publication (2002). In addition, it is inconsistent in numeration compared to the first reference "85(11):2127-37" and the second "Vol. 16, No. 3, pp. 143-149

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Features

- Allows natural surgical procedure: reduce, fill, fix
- Can be drilled and tapped, and screws can be placed through it at any time during or after the setting process
- Provides partial structural support during the healing process
- Reaches a compressive strength of 35 MPa within 24 hours
- Provides more than 40 times the toughness² of Norian SRS
- Isothermic hardening eliminates thermal injury to surrounding soft tissue
- Injectability allows minimally invasive treatment and optimal defect filling.
- Hardens in a wet environment, reducing the need to control moisture at the operative site.



² Toughness is defined as a measure of the material's ability to resist cracking.
Data on file with Synthes.

Norian Drillable Inject

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Basic science

Norian Drillable is a self-setting calcium phosphate bone void filler which:

- Contains resorbable polylactide/glycolide copolymer fibers which reduce crack propagation and allow the material to be drilled and tapped
- Hardens in vivo to carbonated apatite, closely resembling the mineral phase of bone
- Gradually resorbs and is replaced with bone during the healing process
- Is biocompatible and isothermic.

Although hydroxyapatite is commonly thought of as the mineral phase of bone, carbonated apatite actually constitutes 60–70% of total dry bone weight. The main distinction between hydroxyapatite and carbonated apatite is the presence of carbonate. The carbonate content of hydroxyapatite is 0%, while the carbonate content of the carbonated apatite contained in bone is 4–6%. Unlike hydroxyapatite, Norian Drillable has a carbonate content of approximately 4.5%, which closely resembles the composition of bone.



Characteristic	Bone	Norian Drillable
Carbonate content	4.0–6.0%	~4.5%
Ca/P molar ratio	1.33–1.73	1.60
Crystal Order	Low	Low
Perfect crystal size	~200 Å	~200 Å
Chemical make-up	Inorganic/ organic	Inorganic/ organic

Indications and Contraindications

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INDICATIONS

Norian Drillable Inject is 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 Inject can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has set, it acts as a temporary support medium and is not intended to provide structural support during the healing process. Norian Drillable Inject is intended to be placed into bony voids either before or after final fixation.

CONTRAINDICATIONS

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.

Norian Drillable Inject is not intended for use in the spine and should not be used in the presence of active or suspected infection.

Norian Drillable Inject is not for screw augmentation.

Norian Drillable Inject is not for use in:

- Patients with traumatic open injuries that are predisposed to infection
- Stress bearing applications
- Areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implanted rigid fixation hardware.
- Patients with compromised health (e.g. abnormal calcium metabolism, metabolic bone disease, a recent local untreated infection, vascular or severe neurological disease, infection, immunologic deficiencies or systemic disorders) that result in poor wound healing or will result in tissue deterioration over the implant site.
- Patients who are skeletally immature
- Vertebral compression fractures
- Intra-articular space (i.e., material injected into the joint space).

Common applications include:

- Tibial plateau
- Distal femur
- Distal radius
- Proximal humerus
- Calcaneus
- Bone cyst void

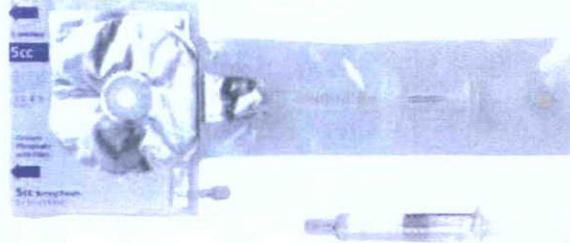
System Overview

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Rotary pouches for rotary mixer

Rotary pouches are designed for mixing at the time of use and are composed of two components:

- Sterile powder in a rotary pouch (calcium phosphate with absorbable polylactide/glycolide copolymer fibers)
- Liquid solution in a syringe (dilute sodium phosphate with sodium hyaluronate)



Rotary pouches are available in various sizes, with a delivery syringe integrated into the rotary pouch.

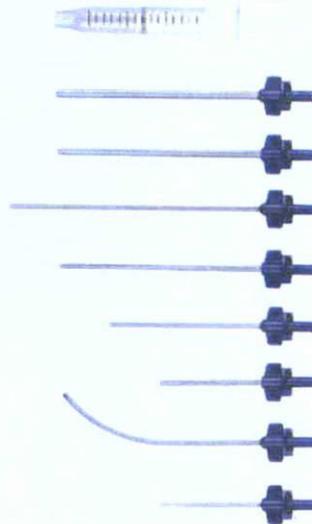
Rotary mixer

The rotary mixer is electrically powered and is used outside the sterile field. Before starting the mixing cycle, the solution component is manually injected into the powder compartment. When the mixing cycle begins, the mixer's roller carriage operates to mix the powder and solution into a paste. When mixing is complete, the rotary pouch is fed through a set of rollers and the paste is mechanically transferred into the delivery syringe.



Delivery syringe

- Included in the sterile rotary pouch
- An easy, precise way to inject the bone void filler
- Compatible with a selection of delivery needles (available in various sizes to meet a variety of surgical needs)
- Single use only



Preoperative Planning

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1

Assess void

Assess the void or defect and plan fracture reduction and stabilization if the void is due to traumatic injury.

2

Determine the surgical approach

Determine the surgical approach (minimally invasive or open) and the delivery method.

3

Prepare void

Irrigate and aspirate the void to clear the injection path for the bone void filler. Prepare the void by compacting the cancellous bone with a curette, elevator or similar instrument.

Technique Tip: The use of warm saline for irrigation can assist in returning the defect site to body temperature.

4

Plan injection path

Preplan the injection path by inserting the delivery needle into the void and probing the far ends of the cavity. It is important to be certain of the backfill injection path since the 2-minute implantation time begins as soon as the filler contacts the cavity wall.

Norian Drillable Rotary Mix Timing Sequence

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Time and temperature properties

The handling properties of Norian Drillable are governed primarily by the ambient temperature of the material as it is mixed and injected. The following timing sequence refers to the specific time and temperature relationships that must be followed for the material to set properly.

Mixing, approximately 70 seconds

Mix the contents of the rotary pouch using the rotary mixer (70 revolutions).

Preparation time, 3 minutes

Three minutes maximum at room temperature (18°–23°C / 64°–73°F). Transfer the mixed Norian Drillable paste into the delivery syringe and transfer the delivery syringe into the sterile field. Attach a delivery needle. Insert the needle into the operative site and begin injection of the bone void filler.

Implantation time, 2 minutes

Two minutes maximum at body temperature (37°C / 98.6°F). Inject the material into the prepared bone void and manipulate as necessary.

Setting time, 10 minutes

Ten minutes at body temperature (37°C / 98.6°F). If a tourniquet is used, release it and lightly irrigate the exposed bone void filler with warm saline or place warm sponges over the implant site.

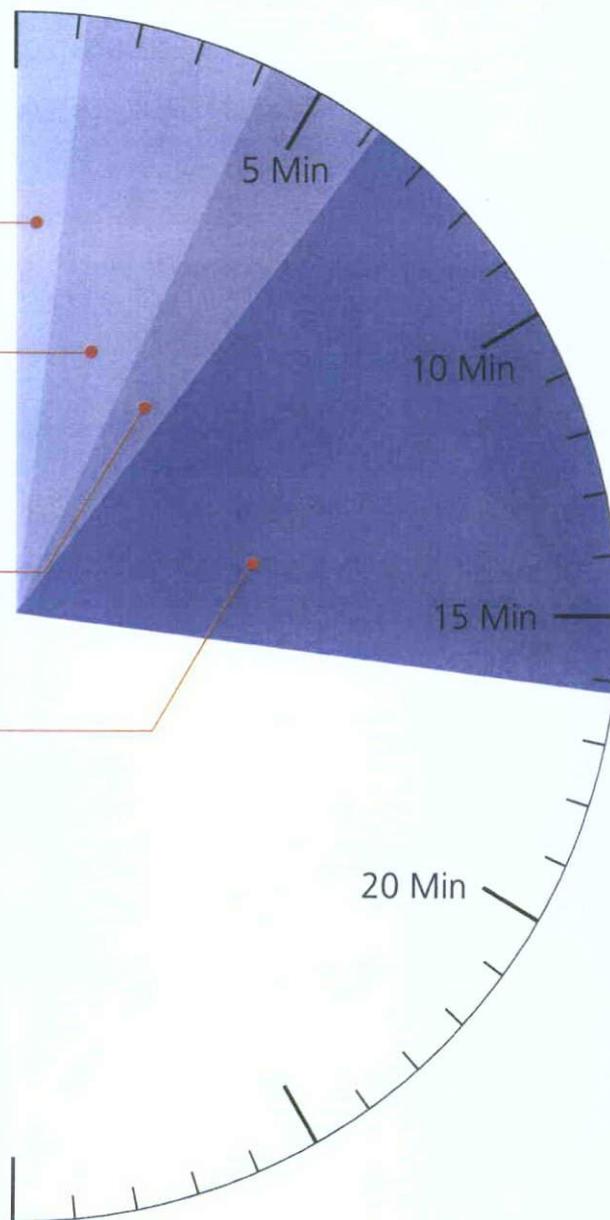
Note: Extremities can cool to well below body temperature during a lengthy open procedure when tourniquet use exceeds one hour. The 10-minute setting period begins once the site has returned to body temperature and the implantation time has expired.

Drilling and screw insertion

The material can be drilled and tapped, and screws can be placed through it at any time during or after the setting process.

Curing time, 24 hours

Twenty-four hours at body temperature (37°C / 98.6°F). Norian Drillable reaches its full compressive strength in 24 hours.



Rotary Mixer Powered Operation

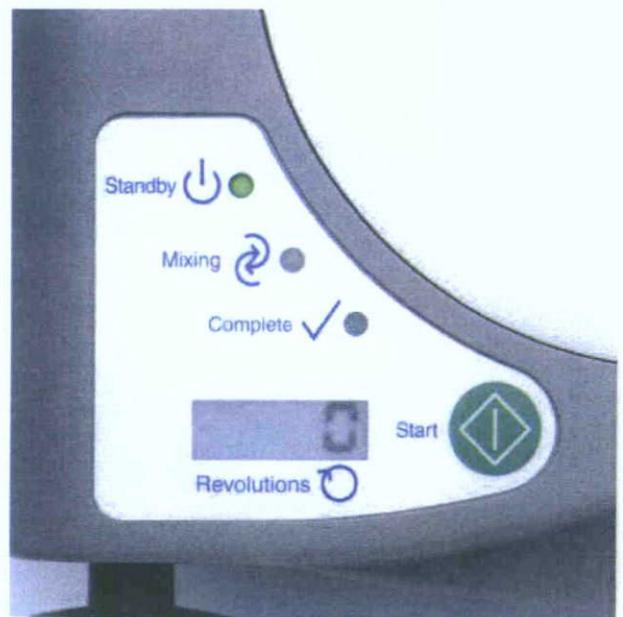
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The following steps are performed outside the sterile field

1

Connect power cord

Unwrap the power cord and connect to an appropriate hospital grade outlet. Once connected, the "Standby" indicator will illuminate, indicating that the unit is ready for operation.



Rotary Mixer Powered Operation

Draft 9/8/10–For Internal Use Only–Not For Distribution

2

Open mixer lid

Open the lid by depressing the thumb latch on the right corner of the lid.



3

Position rotary pouch

Position the rotary pouch on the mixer by aligning the arrows on the rotary pouch and mixer. Press the pouch over the center post of the mixer.



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4

Inject solution

Remove the syringe from the tray.

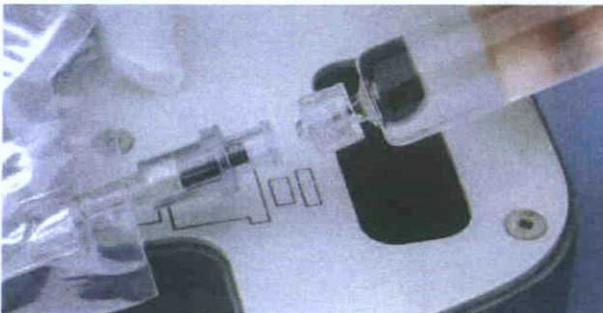
Using aseptic technique, remove the caps from the syringe.



Remove cap from rotary pouch injection port.



Connect the solution syringe to the injection port by turning clockwise.



Inject the entire contents of the solution syringe. Remove the solution syringe after injection is complete.

Note: Once the solution has been injected into the rotary pouch, the remaining steps must be completed immediately.



Rotary Mixer Powered Operation

Draft 9/8/10–For Internal Use Only–Not For Distribution

5

Remove pouch clip

Remove the pouch clip from the rotary pouch and unfold, with the delivery syringe to the right.



6

Close lid and start mixer

Close the lid and secure it by depressing the thumb latch.

Depress the "Start" button. A single brief beep will be heard, the "Standby" indicator will turn off, and the "Mixing" indicator will illuminate.

After 70 revolutions, the mixing cycle is complete. An extended beep will be heard and the "Complete" indicator will slowly flash. The rotary mixer will continue to beep every five seconds until the lid is opened.

Caution: If the rotary mixer fails to complete the mixing cycle, or the lid is opened before the cycle is complete, an audible alarm will sound and all function indicators will flash. Using a new rotary pouch, return to step 2, or mix using manual operation.



Rotary Mixer Manual Operation

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1

Initial steps

Follow steps 2–5 in the powered operation section

2

Close mixer lid

Close the lid and secure by depressing the thumb latch.



3

Operate mixer manually

To operate the mixer manually, lift up on the handle located on the mixer lid until it locks in the upright position. Rotate the top disk 70 revolutions clockwise (approximately one revolution per second)

Note: The counter operates on battery power and will advance when rotating the top disc, without the mixer plugged in.

When mixing is complete, lower the handle on the mixer lid by pulling it up and pushing it to the side.



Preparation (3 minutes)

Draft 9/8/10—For Internal Use Only—Not For Distribution

1

Open mixer lid

Open the lid and lift the mixed rotary pouch from the center post.



2

Transfer paste into delivery syringe

Guide the pouch and turn the knob counterclockwise to feed the rotary pouch into the transfer rollers. The material will be expelled from the mixing chamber into the delivery syringe.



Once the material is completely transferred, turn the transfer knob clockwise to remove the rotary pouch.



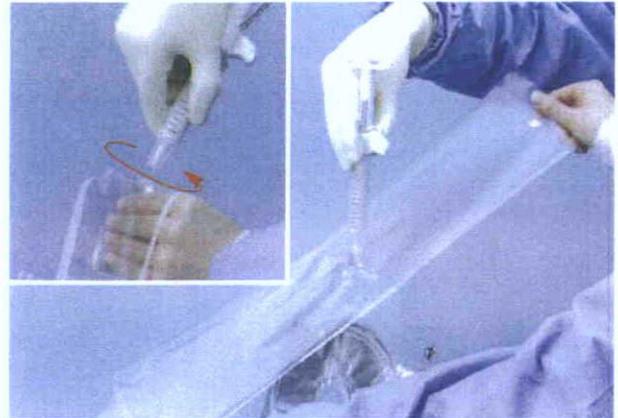
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The following steps are preformed inside the sterile field

3

Transfer delivery syringe to sterile field

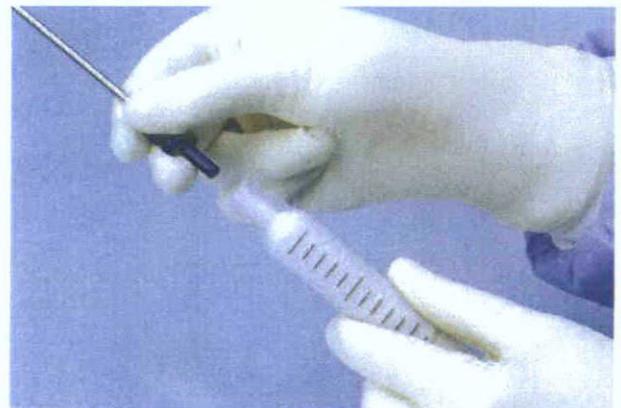
Using aseptic technique, peel back the outer pouch to expose the sterile delivery syringe. A sterile person should detach the delivery syringe with a quarter turn counterclockwise, and complete the transfer to the sterile field.



4

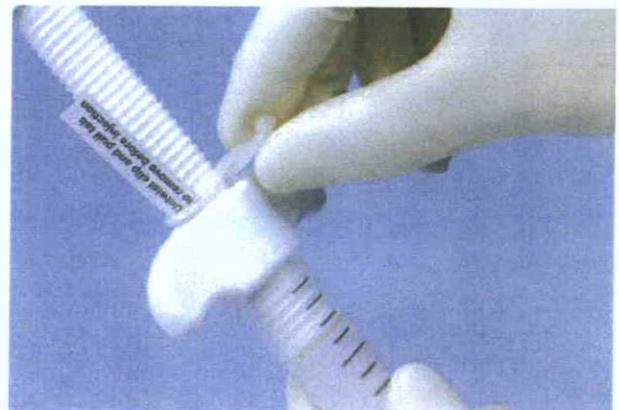
Attach Norian needle

Insert a Norian needle into the connector at the tip of the syringe and attach by rotating a quarter turn clockwise to lock in place.



Remove the clip from the plunger. Slowly depress the plunger to evacuate air from the syringe until a small amount of paste is ejected.

The material is now ready for implantation.



Implantation

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Inject Norian Drillable bone void filler (two methods)

- Always use a backfill technique (see next page). Calibration marks on the delivery syringe are spaced at 1 cc increments.

Inject the material by one of the two methods:

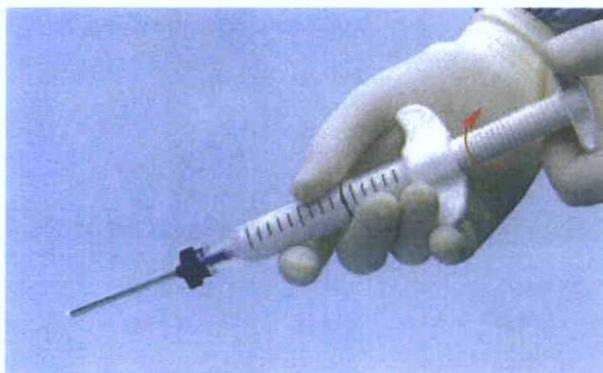
a. Standard injection

Slowly push the plunger. Every click corresponds to 0.5 cc of injected material.

b. Injection under resistance

If you encounter resistance to injection before satisfactory defect filling is achieved, additional injection pressure can be applied by slowly turning the plunger knob clockwise. One full rotation of the knob injects 0.5 cc of material.

Note: At no time during injection should excessive pressure or force be used because this may result in occlusion of the needle or syringe. If resistance is encountered, pull the syringe back slightly and rotate the knob one-half turn counter clockwise to relieve the pressure; then, continue injection.



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Implant Norian Drillable either before or after final fixation

Norian Drillable remains injectable for 2 minutes at room temperature (18°–23°C / 64°–73°F). If 2 minutes have elapsed, the remaining Norian Drillable that has not been implanted should be discarded.

- Injection of the material should be performed under direct visualization or under real-time image intensification. If obstruction of the needle occurs, the needle should be discarded and replaced with a new needle.

Begin injection and slowly withdraw the needle as fill is achieved.

Completely fill the void. Check the fill with multiple views. Remove excess material.

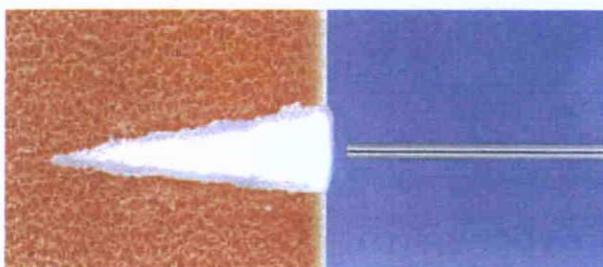
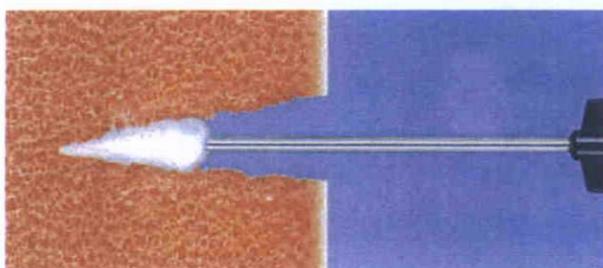
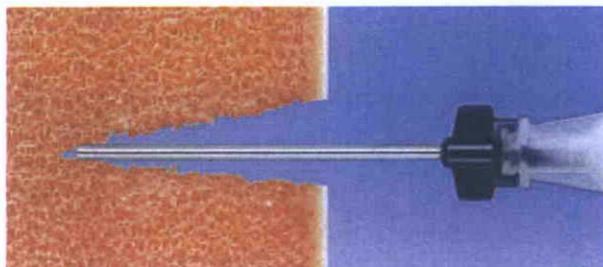
At body temperature (37°C / 98.6°F), Norian Drillable begins to set approximately 2 minutes following implantation.

Avoid extrasosseous deposits of Norian Drillable bone void filler

It is important to limit the amount of material that is allowed to perfuse into the soft tissues and joint space. Irritation or inflammation may be possible complications associated with large extrasosseous deposits of Norian Drillable.

If the material is implanted into the joint or soft tissue, care should be taken to remove the excess material by irrigating it away from the site.

Precaution: If more than one Rotary Pouch, the total volume (not to exceed 40cc) of Norian Drillable liquid should be implanted within the 2-minute Implantation Time.



Drilling and Screw Insertion

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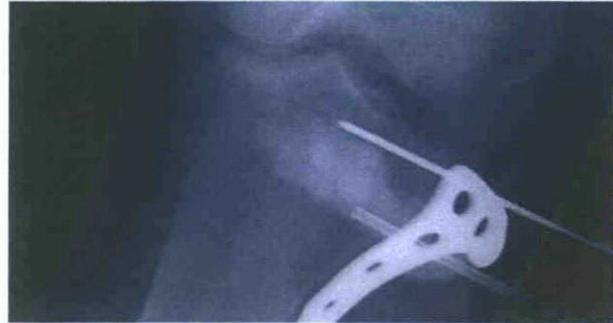
The material can be drilled and tapped, and screws can be placed through it at any time after injection. Norian Drillable should not be used as a screw anchor. Screws placed through the material should be supported by bone on both sides of the material, according to proper orthopaedic reduction technique. Contouring of Norian Drillable can be done manually or with instruments, as desired.

If placing screws through fully set Norian Drillable, a hole should be predrilled to the root diameter of the screw. Do not place self-drilling screws through the material without predrilling to the root diameter.

Proceed slowly and irrigate while drilling through set Norian Drillable. Clear excess material from the flutes of the drill bit. After drilling or tapping through set material, irrigate to remove excess debris.

Placing guide wires (e.g. K-wires) through Norian Drillable may cause the material to fracture. If guide wires are to be used, it is recommended that the guide wire is inserted into Norian Drillable during the 2-minute implantation time or the 10-minute set time. Placing guide wires through the material after the 10-minute set time has elapsed is not recommended.

The use of cannulated screws with thread diameters greater than 5.0 mm over a guide wire is not recommended.



Setting and Curing

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Release the tourniquet, if used, and gently irrigate with warm saline to return the operative site to core body temperature. At body temperature (37°C / 98.6°F), Norian Drillable may be considered set 10 minutes after implantation is completed.

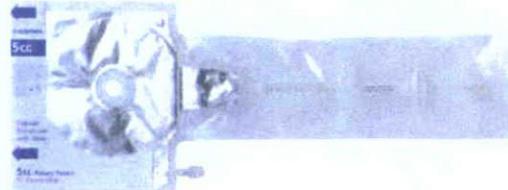
Alternatively, to aid in the reduction of the fracture site, Norian Drillable can be allowed to set before application of final fixation materials. See chapter "Drilling and Screw Insertion".

Norian Drillable fully cures and reaches its ultimate compressive strength within 24 hours.

Product Information

Draft 9/8/10–For Internal Use Only–Not For Distribution

07.704.003S Norian Drillable Inject, sterile 3 cc
 07.704.005S 5 cc
 07.704.010S 10 cc

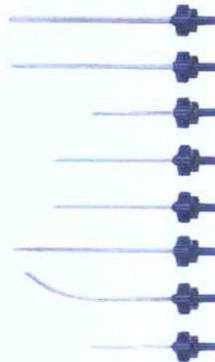


MXR-US-2000 Rotary Mixer



Delivery Needles, sterile

Single Pack	5 Pack	
DLS-7183-01S	DLS-7083-05S	8 gauge×10 cm
DLS-7103-01S	DLS-7103-05S	10 gauge×10 cm
n/a	DLS-7121-05S	12 gauge×5 cm
DLS-7122-01	DLS-7122-05S	12 gauge×7.5 cm
DLS-7123-01	DLS-7123-05S	12 gauge×10 cm
n/a	DLS-7124-05S	12 gauge×12.5 cm
DLS-7126-01	DLS-7126-05S	12 gauge×10 cm, curved
n/a	DLS-7141-05S	14 gauge×5 cm



Also Available

07.704.103S Norian Drillable Fast Set Putty, sterile 3 cc
 07.704.105S 5 cc
 07.704.110S 10 cc



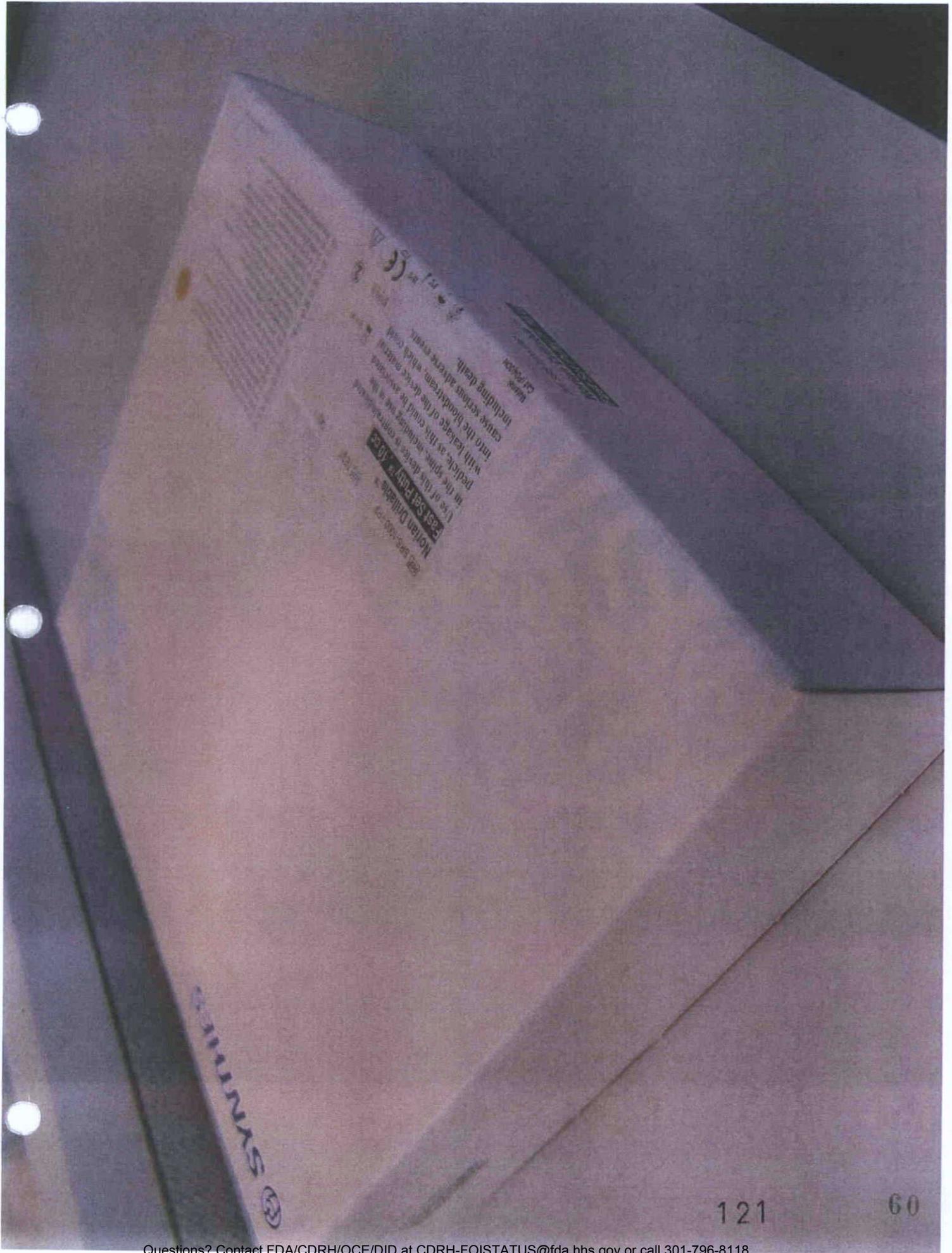
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1302 Wrights Lane East
West Chester, PA 19380
Telephone: (610) 719-5000
To order: (800) 523-0322
Fax: (610) 251-9056

Synthes (Canada) Ltd.
2566 Meadowpine Boulevard
Mississauga, Ontario L5N 6P9
Telephone: (905) 567-0440
To order: (800) 668-1119
Fax: (905) 567-3185

www.synthes.com



Caution
Risk of spinal device leakage, which could
cause serious adverse events,
including death.
Leakage of the device material
into the bloodstream, which could
affect the spine, including the
vertebrae, as the device material
leaks out of the device.
The risk of spinal device leakage is
increased in the spine, including the
vertebrae, as the device material
leaks out of the device.

SYNTHES

DRILLING

FOR USE ONLY FOR SPINAL TEST QTY 1

**Norian Drillable™
Fast Set Putty™, 10 cc**

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.

Material:
CaS (PO)3OH

25°C
9°C

SRS-1000-FRP

**Norian Drillable™
Fast Set Putty™, 10 cc**

2016.08

STERILE

CE 0123



EN: This device is contraindicated for use 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.
 FR: Ce dispositif est contre-indiqué pour une utilisation dans la colonne vertébrale, y compris dans le pédicule, car cela pourrait être associé à une fuite de matériel dans le sang, ce qui pourrait entraîner des événements graves, y compris la mort.
 DA: Dette apparat er kontraindiceret til brug i ryggen, herunder brug i pedikler, da dette kan være forbundet med udslæp af apparatets materiale i blodbanen, hvilket kan medføre alvorlige helsebegivenheder, herunder død.
 NL: Het apparaat is gecontraïndiceerd voor gebruik in de wervelkolom, met name in de pedicel, omdat dit kan leiden tot lekkage van het apparaatmateriaal in de bloedbaan, wat ernstige bijwerkingen kan veroorzaken, inclusief de dood.
 SK: Nepoužívajte, ak je indikátor teploty červený.
 FI: Käytä vain selkässä, ei selkärangan osissa, mukaan lukien pedikeli, koska tämä voi aiheuttaa välikappaleen vuotamista verenvirtaan, mikä voi aiheuttaa vakavia seurauksia, mukaan lukien kuoleman.
 BG: Използвайте само в гръбначния стълб, включително в педикелите, тъй като това може да бъде свързано с изтичане на материала на устройството в кръвообращението, което може да причини сериозни неблагоприятни събития, включително смърт.
 HU: Tilos fellhasználni, ha a hőmérőjelző mutatók pirosak.
 HR: Ne upotrebljavati ako pokazatelj temperature pokazuje crnu.
 RO: A nu se folosește decât în regiunile de temperatură indicată.
 TR: Sıcaklık göstergesi siyah renkte ise kullanılmayın.
 SV: Använd inte om temperaturindikatorn är svart.
 CS: Nepoužívejte, pokud má indikátor teploty červenou barvu.

20-2462-A 10030-A

EN Do not use if temperature indicator
 DE Nicht verwenden, wenn der Temperaturindikator
 ES No utilizarlo si el indicador de temperatura
 FR Ne pas utiliser si le témoin de température
 IT Non utilizzare se l'indicatore di temperatura
 PT Não utilize se o indicador de temperatura
 DA Må ikke anvendes, hvis temperaturindikator
 NL Niet gebruiken als de temperatuurindicator
 EL Μην χρησιμοποιείτε το προϊόν εάν ο δείκτης της θερμοκρασίας
 SK Nepoužívejte, ak je indikátor teploty
 FI Tuotetta ei saa käyttää, jos lämpömittari näyttää
 PL Nie stosować jeśli wskaźnik temperatury
 BG Да не се използва, ако температурният индикатор
 HU Tilos felhasználni, ha a hőmérő jelzi
 HR Ne upotrebljavati ako je temperatura
 RO A nu se folosește dacă indicatorul de temperatură
 TR Sicaklik göstergesi sıcaklık göstergesi
 SV Använd inte om temperaturindikatorn
 CS Nepoužívejte, pokud je indikátor teploty

REF SRS-1000-FRP

LOT TEST

Qty. 1

Norian Drillable™

Fast Set Putty™, 10 cc

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.

Material:
 Ca5 (PO4)3OH

25°C
 5°C

2010-08

STERILE

CE 0123



 **SYNTHES**

Small 6RS-1000 PVI
Norian Drillable™
10 cc

SYNTHES
10 cc

126

REF SRS-1000-FRI

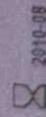
Qty. 1

LOT TEST

Norian Drillable™

10 CC

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.



STERILE

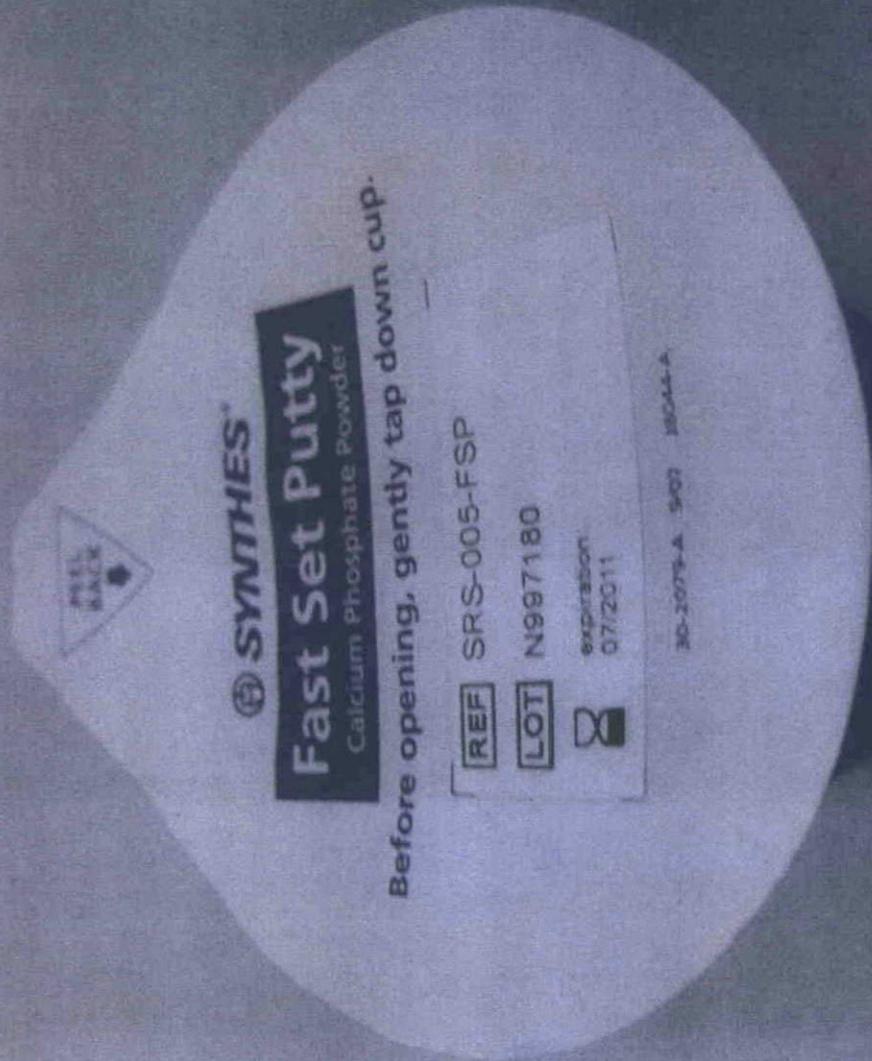


REF SRS-1000-FRI

- EN Do not use if temperature indicator is black
- DE Nicht verwenden, wenn der Temperaturindikator schwarz ist
- ES No utilizarlo si el indicador de temperatura está de color negro
- FR Ne pas utiliser si le témoin de température est noir
- IT Non utilizzare se l'indicatore di temperatura è nero
- PT Não utilize se o indicador de temperatura estiver de cor preta
- DA Må ikke anvendes, hvis temperaturindikatoren er sort
- NL Niet gebruiken als de temperatuurindicator zwart is
- EL Μην χρησιμοποιείτε το προϊόν σε περίπτωση που η ένδειξη της θερμοκρασίας έχει μείνει μαύρη.
- SK Nepoužívajte, ak je indikátor teploty čierny
- FI Tuotetta ei saa käyttää, jos lämpötilaosoitin on väriltään musta.
- PL Nie stosować jeśli wskaźnik temperatury jest czarny
- BG Да не се използва, ако индикаторът за температура е черен
- HU Tilos felhasználni, ha a hőmérséklet-indikátor fekete
- HR Ne upotrebljavati ako pokazatelj temperature pokazuje crno
- RO A nu se folosi dacă indicatorul de temperatură este negru
- TR Sıcaklık göstergesi siyah renkte ise kullanmayın
- SV Använd inte om temperaturindikatorn är svart
- CS Nepoužívejte, pokud má indikátor teploty černou barvu.

20-1062-A 15000-A

65



PEEL BACK
↓

1



Top cap with hand surface. Then slowly peel back lid.

Arbeitsgehäuse vorsichtig abheben. Danach langsam Verschluss vorsichtig abheben.

Coverage separarmente el recipiente sobre una superficie lisa y retirar lentamente la tapa.

Richiettare la vaschetta su una superficie liscia poi aprire lentamente il coperchio.

Apertur la capote sur une surface dure et retirer délicatement le film de couverture.

Retira con a taca sobre uma superfície rígida e, em seguida, retire lentamente a cobertura.

2



Ado entire contents of solution syringe. Eye's slowly.

Den gesamten Spritzeninhalt zutügen. Langsam bewegen.

Añada todo el contenido de la jeringa con cuidado. Expulse lentamente.

Aggiungere tutto il contenuto della siringa con la soluzione. Espellere velocemente.

Ajouter le contenu complet de la seringue de solution. Éjecter lentement.

Adicione todo o conteúdo da seringa com a solução. Ejecte lentamente.

3



Mix vigorously with spatula for 45-90 seconds until a smooth putty is formed.

Mit dem Spachtel 45-90 Sekunden kräftig mischen, bis eine glatte Spachtelmasse entstanden ist.

Miscure vigorosamente con una spatola durante 45 a 90 segundos, hasta que se forme una masa uniforme.

Miscelare vigorosamente con la spatola per 45-90 secondi fino ad ottenere una pasta uniforme.

Mélanger énergiquement avec la spatule pendant 45-90 secondes jusqu'à l'obtention d'une pâte homogène.

Misture vigorosamente com a espátula durante 45-90 segundos, até se formar uma massa homogênea.

Fast Set Putty

Fast Set Putty

Contains:

- Powder sealed in Mixing Cup
- Spatula



**WARNING: DO NOT REUSE THIS PRODUCT. CONTENTS STERILE. LEAKS PACKAGE
 CAUSES OR DANGERS. SINGLE USE ONLY. DO NOT REUSE.
 IMPORTANT: The tray containing product cannot be stored unless the
 other parts have been opened.**

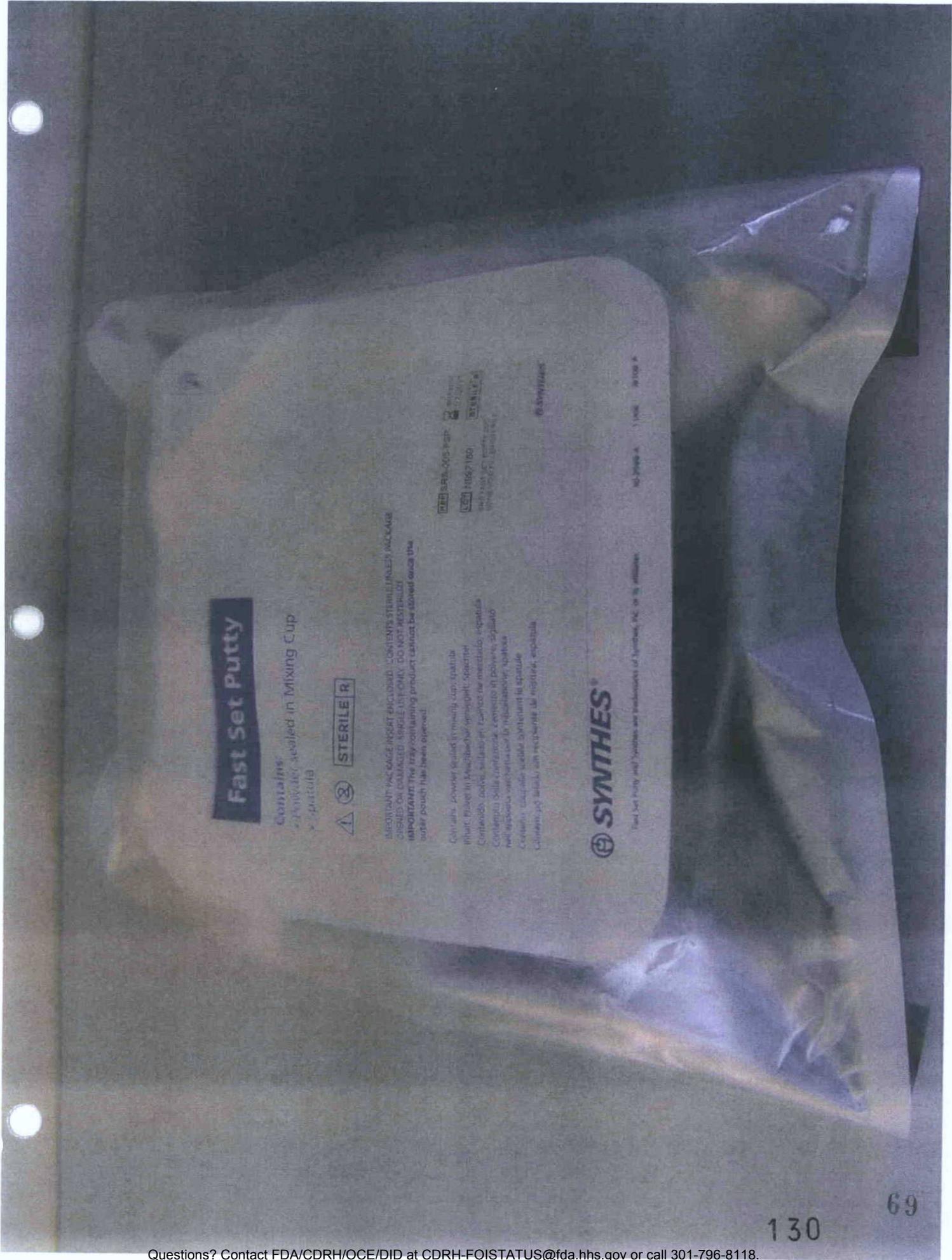
Contiene: polvere sigillata in mixing cup; spatula
 Inhalt: Pulver in Mischbecher; Spatula
 Contenido: polvo, sellado en el recipiente de mezcla; espátula
 Contenuto dalla confezione: contenuto in polvere; spatola
 nell'apposita vaschetta per la miscelazione; spatola
 Contenu: poudre scellée contenant la spatule
 Contenu: pó de polvo em recipiente de mistura; espátula



Fast Set Putty and Spatulas are trademarks of Synthes, Inc. or its affiliates.

STERILE
 LOT# 1607180
 05/2014
 SYNTHES

30-3000-A 1100 0100 A



Fast Set Putty

Contains:
Powder sealed in Mixing Cup
+ spatula

STERILE



IMPORTANT! PAC GAGE INSERT ENCLOSED. CONTENTS STERILE/PAKEY PACKAGE
DAMAGED OR DAMAGED. HANDLE ONLY. DO NOT RESTERILIZE!
IMPORTANTE! THE TRY CONTAINING PRODUCT CANNOT BE STERILIZED SINCE THE
outer pouch has been opened.

Contains: powder sealed in mixing cup, spatula
elettro ricambi in plastica/impugnatura, spatola
Contiene: polvere sigillata in bustina, spatola
Contiene: polvere sigillata in bustina, spatola
nell'inserto con bustina di ricambi/impugnatura
Contiene: polvere sigillata in bustina, spatola

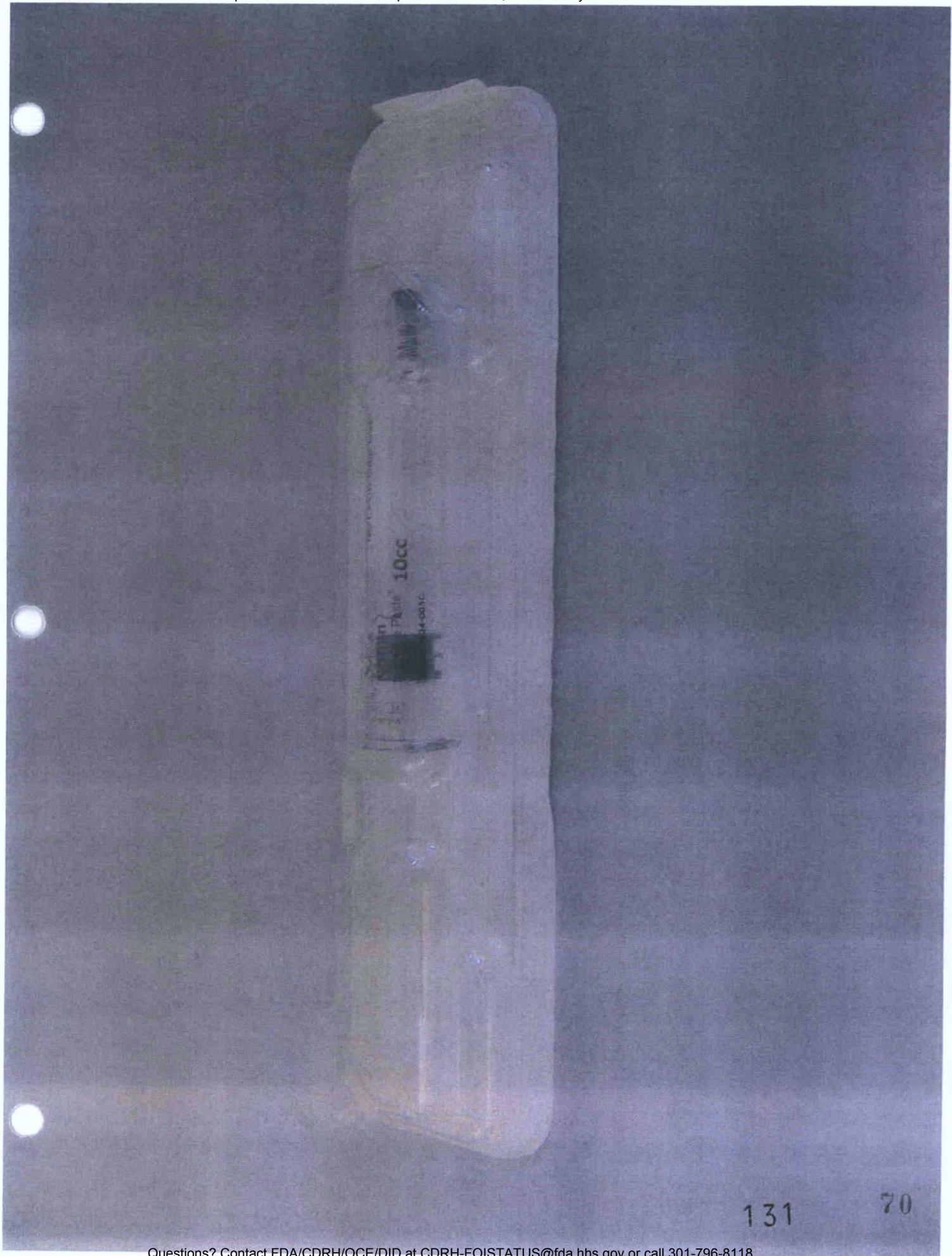
SYNTHES

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USA: 800-595-7337
USA: 856-2700
USA: 800-595-7337
USA: 856-2700

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NO. 2999 A 1/100 39 100 A



Solution Syringe PTQ TEST

SYNTHES

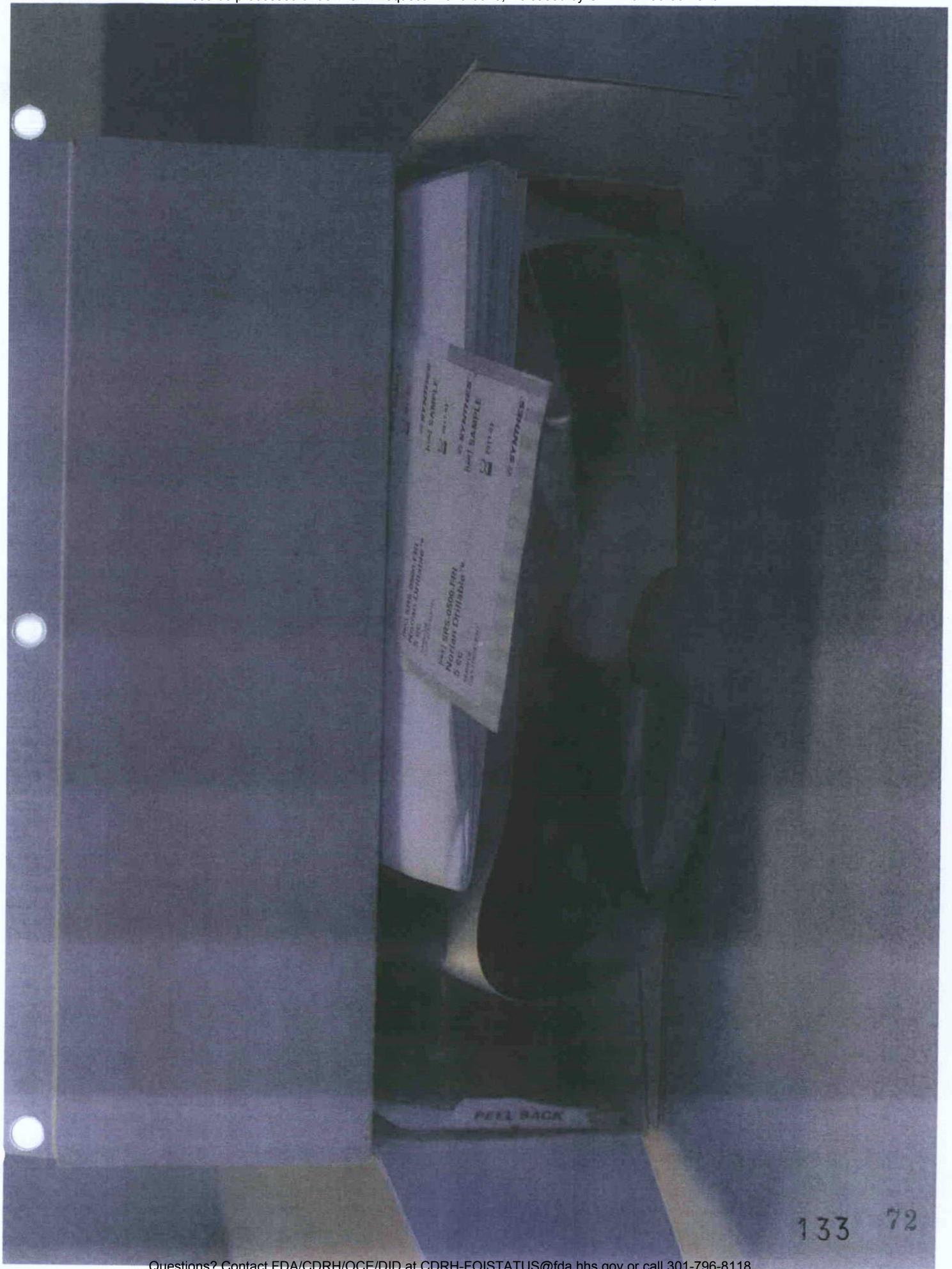
20151011A 2508 JB448A

STERILE A STERILE EO

IMPORTANT: PACKAGE INSERT ENCLOSED.
CONTENTS STERILE UNLESS PACKAGE OPENED OR DAMAGED.
SINGLE USE ONLY. STORE AT TEMPERATURE RANGE INDICATED.



30-21011-A 2508 JB448-A



133 72



STERILE A STERILE EO

IMPORTANT:
READ ACCOMPANYING PACKAGE INSERT
CONTENTS STERILE (UNLESS PACKAGE
OPENED OR DAMAGED). SINGLE USE ONLY.
STORE AT ROOM TEMPERATURE.
CAUTION: Federal (USA) law restricts this device
to sale by or on the order of a physician.

DA05 JS008-A

Distributed by:

SYNTHES

1101 Synthes Avenue
Monument, CO 80132

30-0109-A

SRS-010-FRS

LOT: N857302

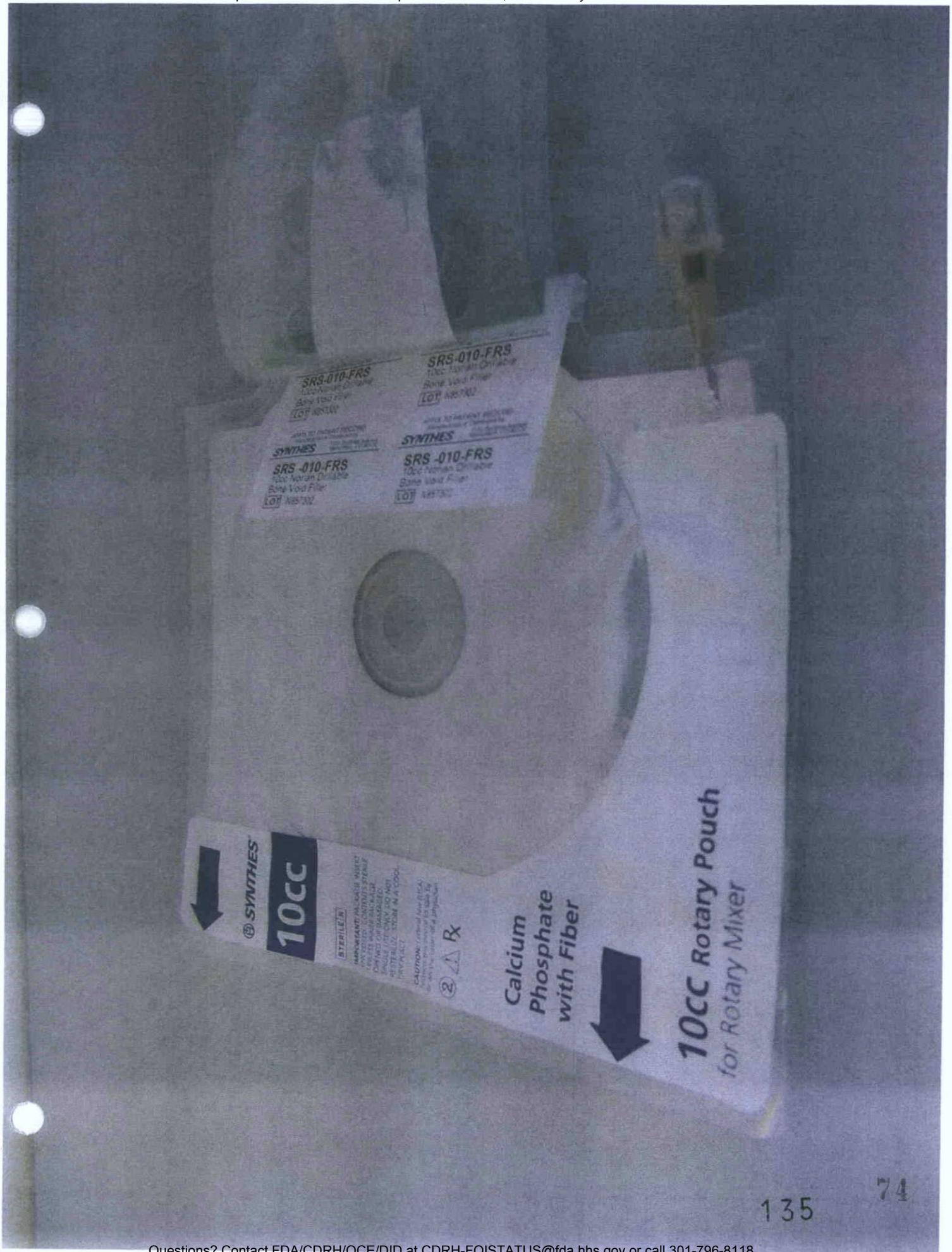
EXP: 2009-03

Solution Syringe

FOR CLINICAL INVESTIGATION
USE ONLY

SYNTHES

20-0419-B 424078





136

75

Calcium Phosphate with Fiber

1. Ouvrir le sachet et verser le contenu dans le récipient approprié.

2. Verser l'eau dans le récipient approprié.

3. Mélanger le contenu du sachet avec l'eau.

4. Verser le contenu du récipient dans le récipient approprié.

5. Mélanger le contenu du récipient avec l'eau.

6. Verser le contenu du récipient dans le récipient approprié.

7. Mélanger le contenu du récipient avec l'eau.

8. Verser le contenu du récipient dans le récipient approprié.

9. Mélanger le contenu du récipient avec l'eau.

SYNTHES

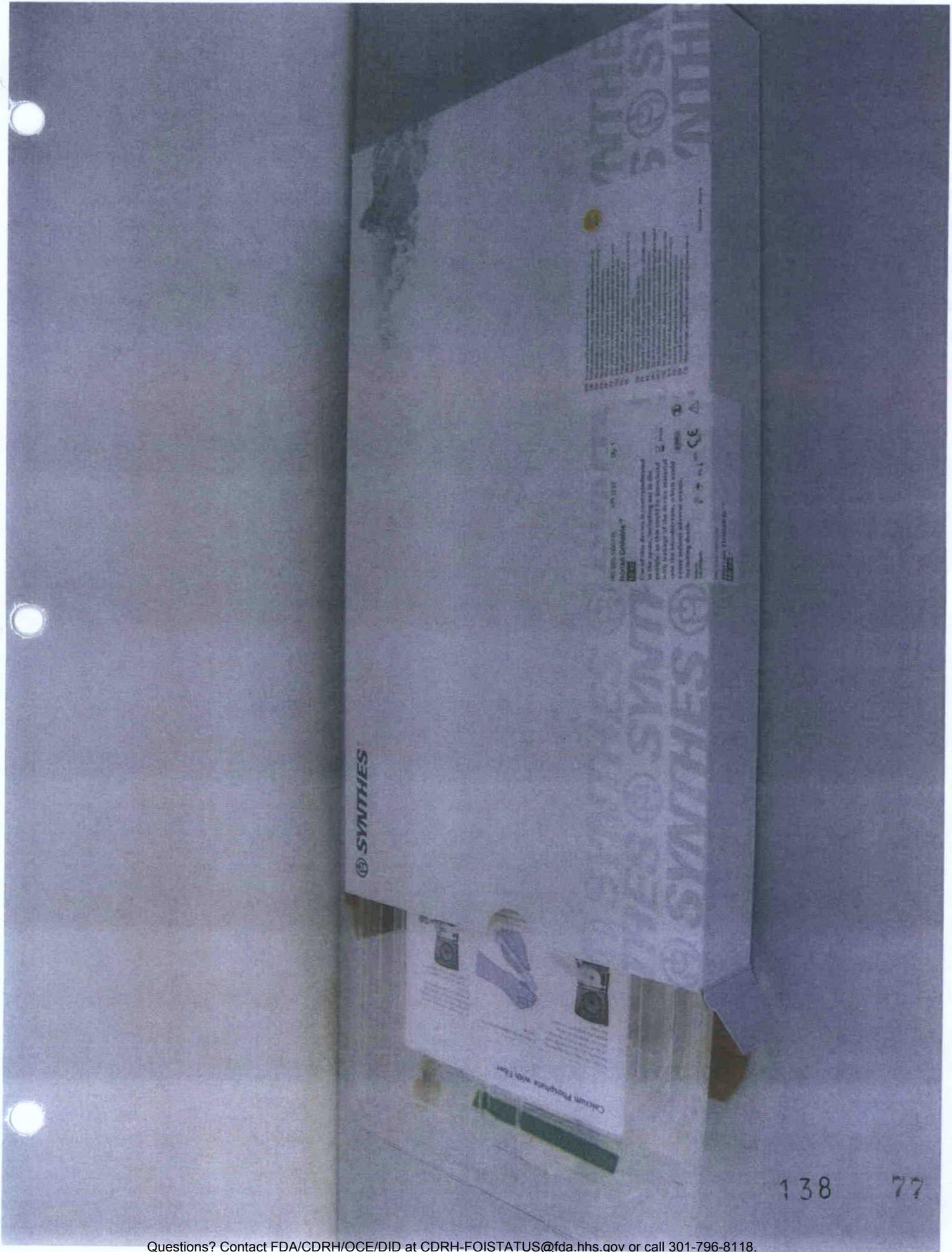
Rotary Pouch

100% POLYPROPYLENE
NON TOXIC
NON ALLERGENIQUE
NON OXYDANT
NON INFLAMMABLE
NON CORROSIF

SYNTHES
1111 Jimmy A. Frank
Mantoloking, NJ 07020

SRS 010-FRS
LOT: M85730
EXP: 03/08-03

Solution Syringe
FOR ORAL USE ONLY
SYNTHES



138

77



COVER SHEET MEMORANDUM

From: Reviewer Name

Subject: 510(k) Number

To: The Record

[Handwritten signature]
K102722/S2

Please list CTS decision code SE

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age <=21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days -< 2 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Child (2 years -< 12 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Adolescent (12 years -< 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	✓

Regulation Number 888.3046 Class* II Product Code ~~RETB~~ meu

Additional Product Codes: ~~RETB~~ OIS (*If unclassified, see 510(k) Staff)

Review: [Signature] (Branch Chief) RETB (Branch Code) 1/27/11 (Date)

Final Review: [Signature] (Division Director) [Signature] (Date)

Dec 11
1/27/11

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K102722 .

Date: January 18, 2011

To: The Record

From: Nadine Y. Sloan, Biomedical Engineer

Office: ODE

Division: DGNRD/OSDB

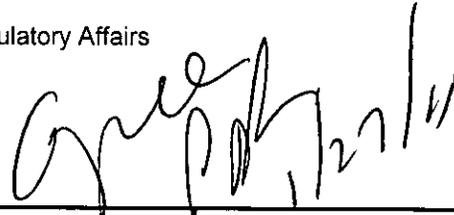
510(k) Holder: Synthes

Device Name: Norian Drillable Inject and Norian Drillable Fast Set Putty

Contact: Jeffrey L. Dow, JD, Director of Clinical and Regulatory Affairs

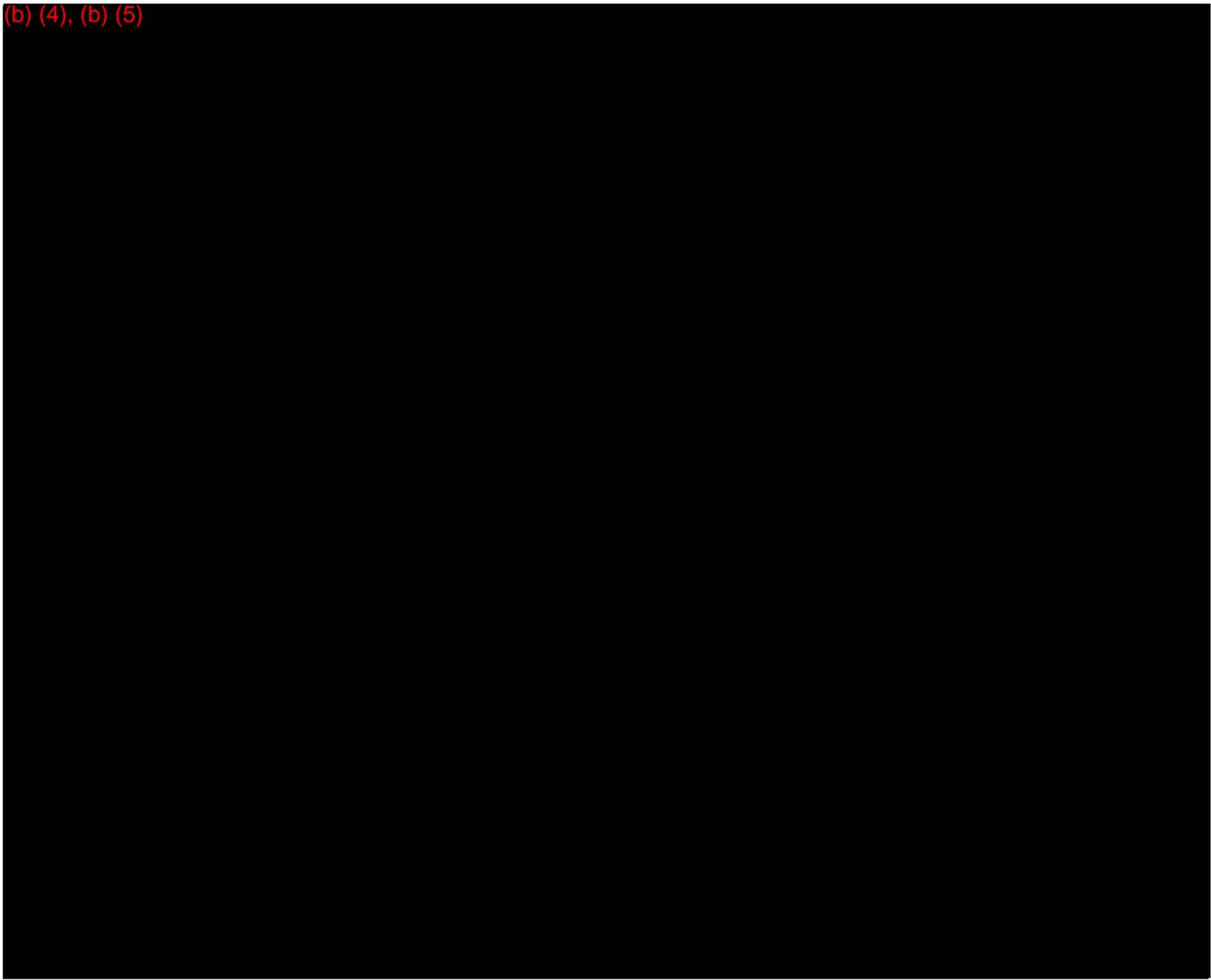
Phone: 484.356.9720

Email: dowj@synthes.com

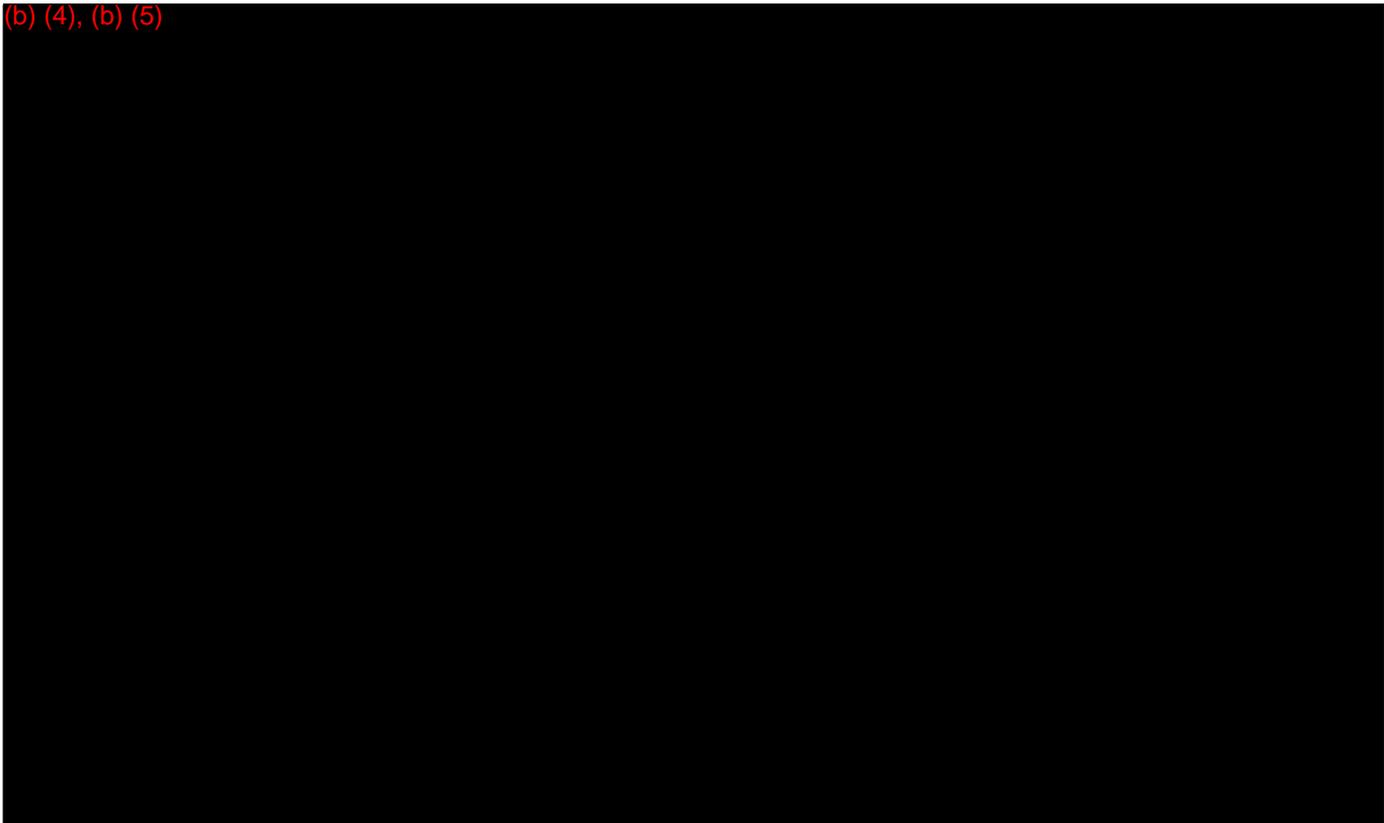


Recommendation: Substantial Equivalence

(b) (4), (b) (5)



(b) (4), (b) (5)



II. Administrative Requirements

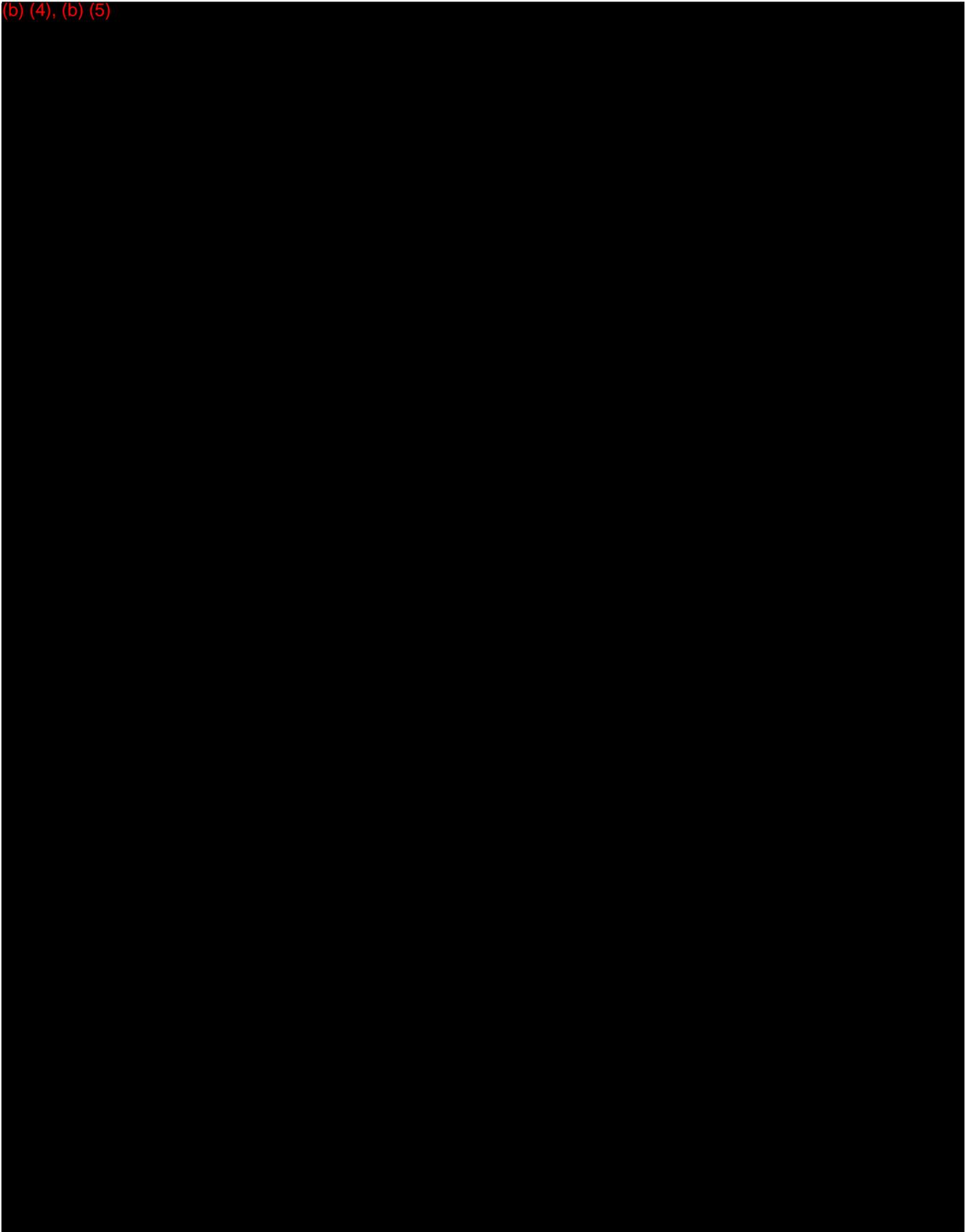
	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

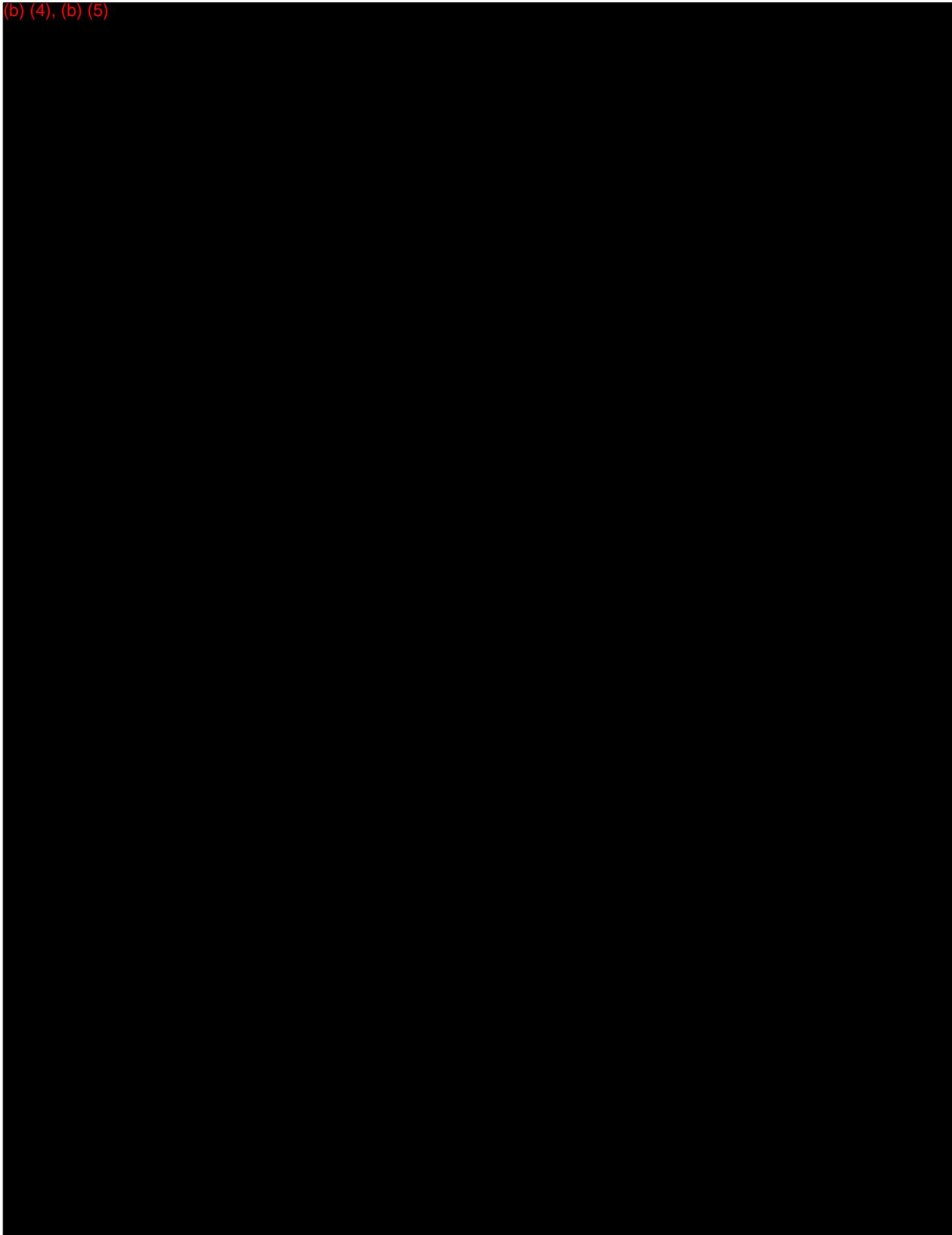
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user?		X	

Devices are identical to the predicate, K073303, the submission is for a package labeling change only (device components packaged inside the outer box, which clearly bears all of the required labeling statements, including the contraindications specifically required per the SE with Limitations).

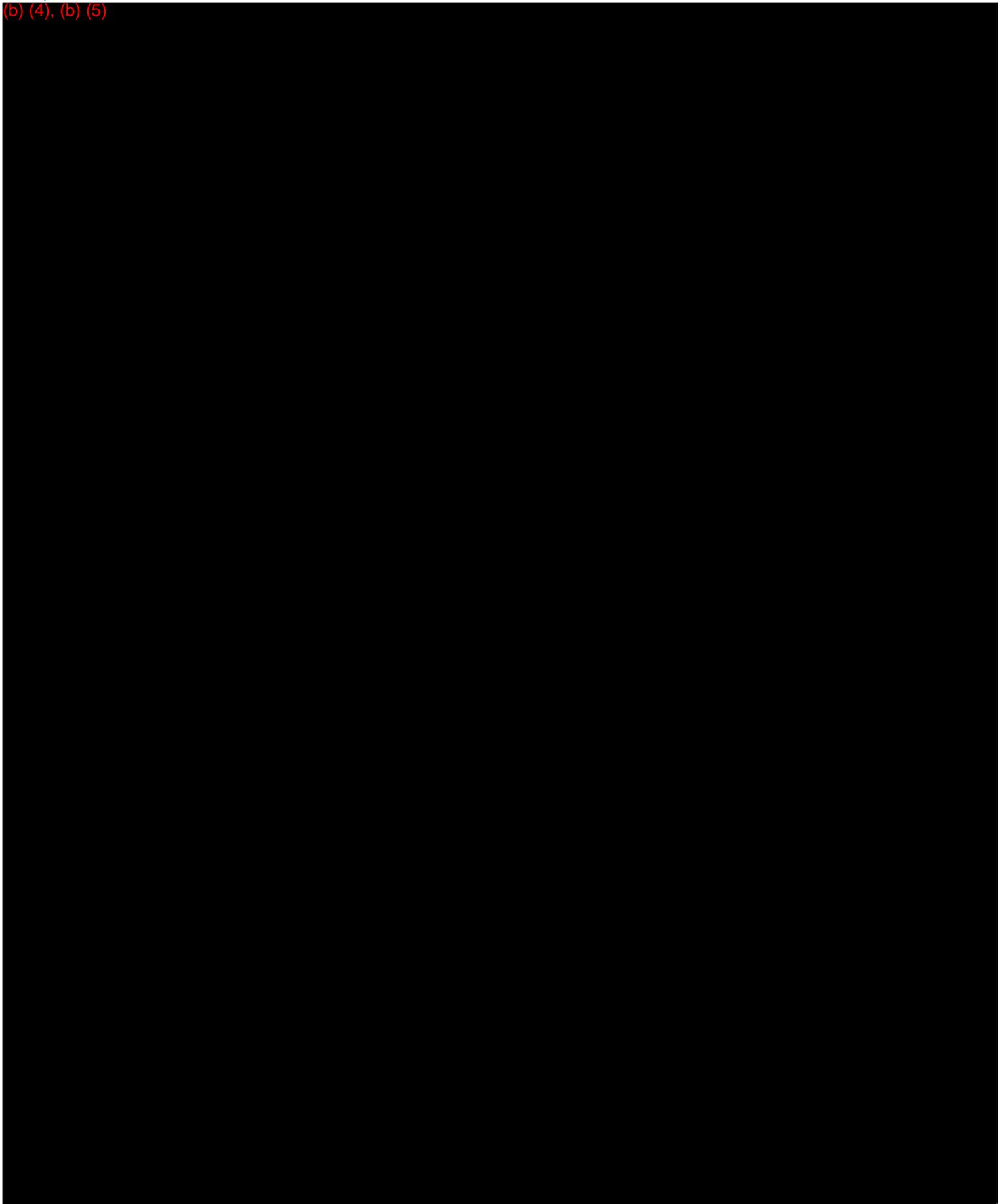
(b) (4), (b) (5)



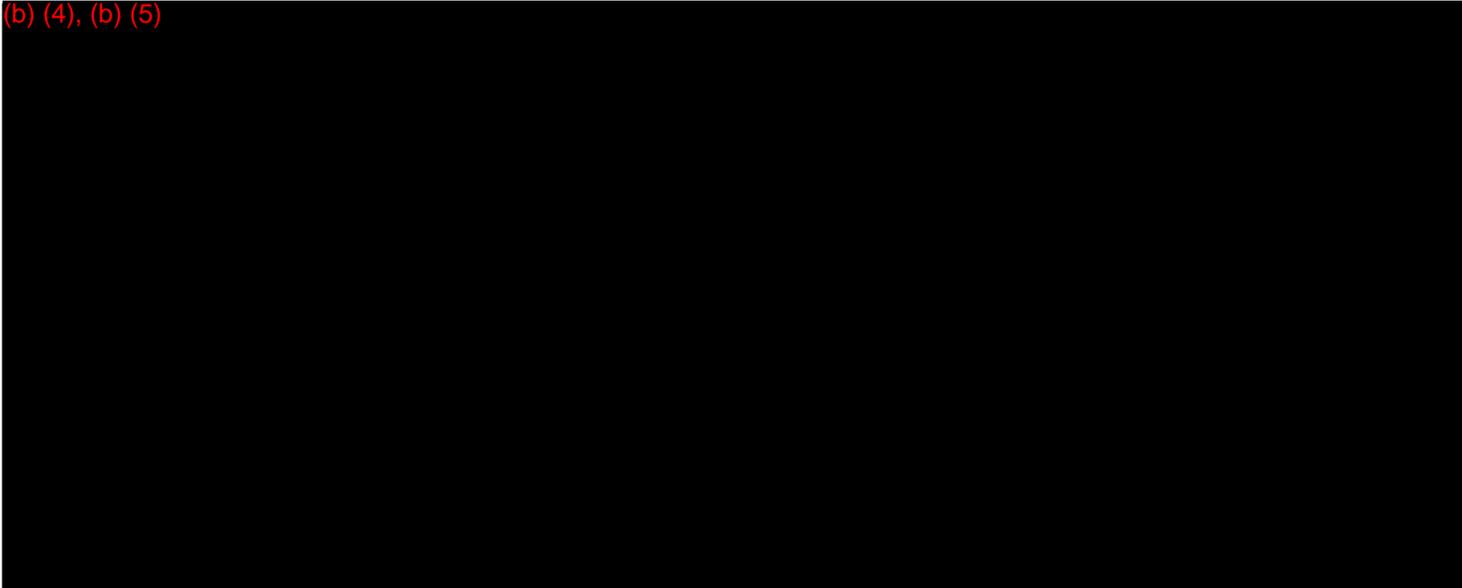
(b) (4), (b) (5)



(b) (4), (b) (5)



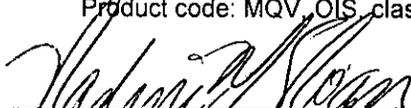
(b) (4), (b) (5)



XVI. Recommendation

Substantial Equivalence

Product code: MQV, OIS, class II, CFR 888.3045

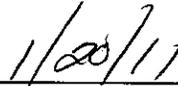


Reviewer



Branch Chief





Date



Date

Sloan, Nadine Y.

From: Dow.Jeff@synthes.com
Sent: Wednesday, January 19, 2011 4:14 PM
To: Sloan, Nadine Y.
Subject: RE: date correction

Nadine:

My sincere apologies. I don't know where that date comes from, but it's on my copy of the cover letter, too. I hereby confirm that the correct date of our response is January 14, 2011.

Jeff

From: Sloan, Nadine Y. [mailto:Nadine.Sloan@fda.hhs.gov]
Sent: Wednesday, January 19, 2011 4:06 PM
To: Dow, Jeff - United States, West Chester
Subject: date correction

Hello Jeff,

I am in receipt of your additional information and see that you dated the cover letter December 14, 2011, when it should be sometime after January 10 (our phone call), presumably January 14... Could you please reply to this e-mail with the correct date and I will add your e-mail to the file.

Thank you,
Nadine

Sloan, Nadine Y.

From: Sloan, Nadine Y.
Sent: Thursday, January 13, 2011 11:44 AM
To: 'Dow.Jeff@synthes.com'
Subject: RE: K102722 Norian Drillable labeling

Dear Jeff,

Yes, the language you propose is satisfactory for the carton components.

I will look forward to your response next week.

Thank you.

Nadine

From: Dow.Jeff@synthes.com [mailto:Dow.Jeff@synthes.com]
Sent: Thursday, January 13, 2011 11:28 AM
To: Sloan, Nadine Y.
Cc: Richardson.Dale@synthes.com; Stadtmiller.Allen@synthes.com; Brown.Vernon@synthes.com
Subject: K102722 Norian Drillable labeling

Dear Nadine:

Here is the language that Synthes proposes to add to the carton components:

"See accompanying Directions for Use for complete indications and contraindications."

Is this language satisfactory? If so, I will use this language in Synthes' complete response to your earlier email, and will send you that response early next week.

Regards,

Jeff

Sloan, Nadine Y.

From: Sloan, Nadine Y.
Sent: Thursday, January 06, 2011 5:53 PM
o: 'Dow.Jeff@synthes.com'
Subject: RE: your 510(k) supplement

Hello Jeff,

(b)(4)



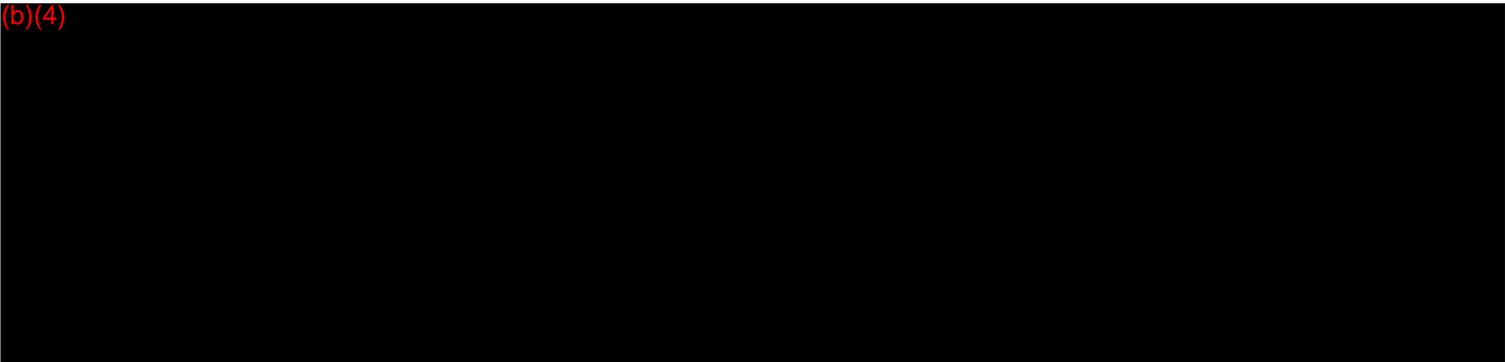
Sincerely,

Nadine

From: Sloan, Nadine Y.
Sent: Thursday, January 06, 2011 3:38 PM
To: 'Dow.Jeff@synthes.com'
Subject: your 510(k) supplement

Hello Jeff,

(b)(4)



Thanks,

Nadine
301-796-6430



COVER SHEET MEMORANDUM

From: Reviewer Name

Subject: 510(k) Number

To: The Record

William Spear

K102722/S1

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%20202%2007.doc)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

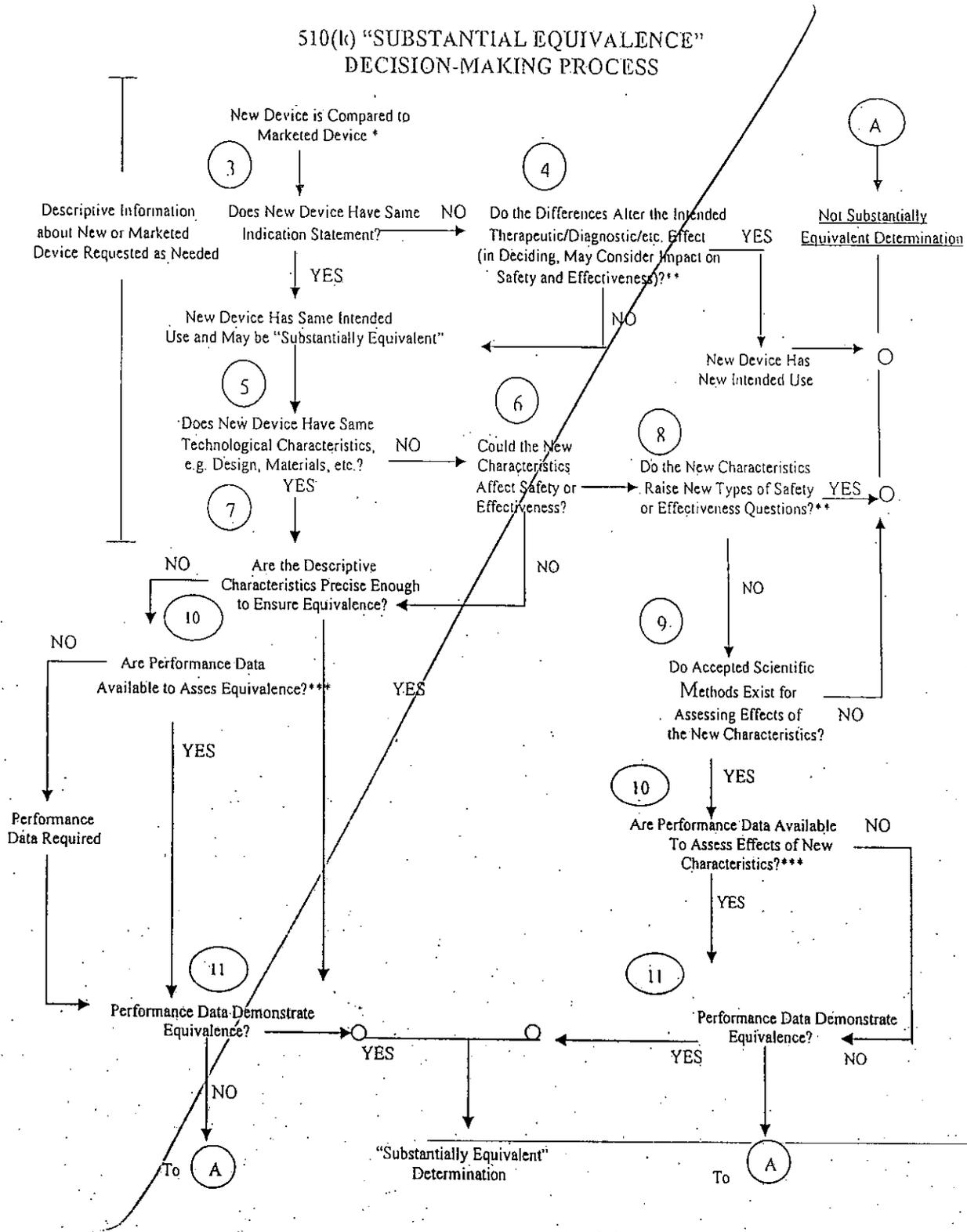
Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____ see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <= 21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days - < 2 years old)			
Child (2 years - < 12 years old)			
Adolescent (12 years - < 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		
Nanotechnology		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)		Contact OC.
Regulation Number	Class*	Product Code

Additional Product Codes: _____ (*If unclassified, see 510(k) Staff)

Review: _____
(Branch Chief) **RETB** (Branch Code) **1/6/11** (Date)

Final Review: _____
(Division Director) (Date)



❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or call 301-796-8118.

Sloan, Nadine Y.

From: Sloan, Nadine Y.
nt: Thursday, January 06, 2011 5:53 PM
o: 'Dow.Jeff@synthes.com'
Subject: RE: your 510(k) supplement

CONCUR
[Signature]
1/6/11

Hello Jeff,

(b)(4)



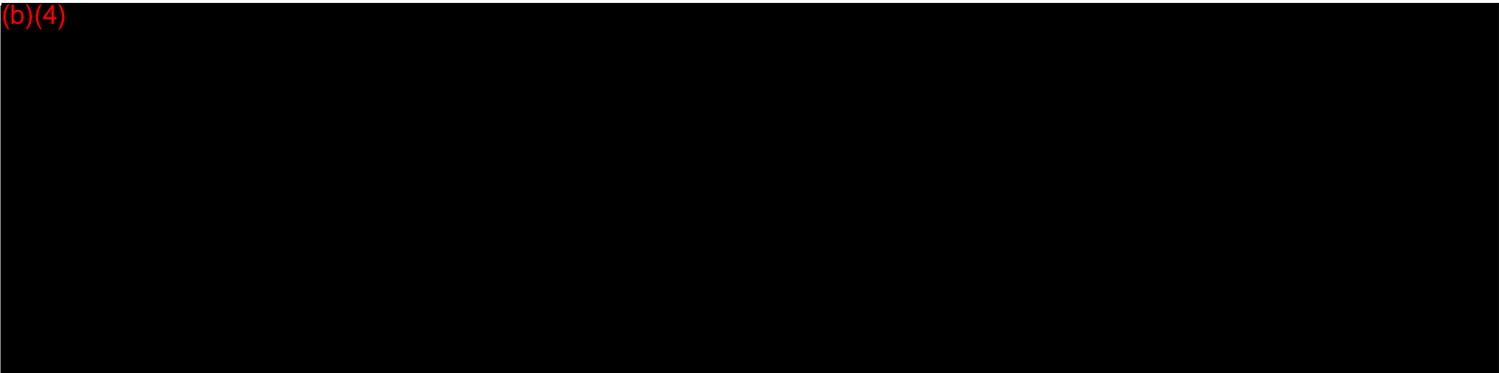
Sincerely,

Nadine

From: Sloan, Nadine Y.
Sent: Thursday, January 06, 2011 3:38 PM
To: 'Dow.Jeff@synthes.com'
Subject: your 510(k) supplement

Hello Jeff,

(b)(4)



Thanks,

Nadine
301-796-6430



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name *Nadine J. Sloan*
Subject: 510(k) Number *K102725*
To: The Record

- Please list CTS decision code *AT*
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%20%202%2007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)
Nanotechnology
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

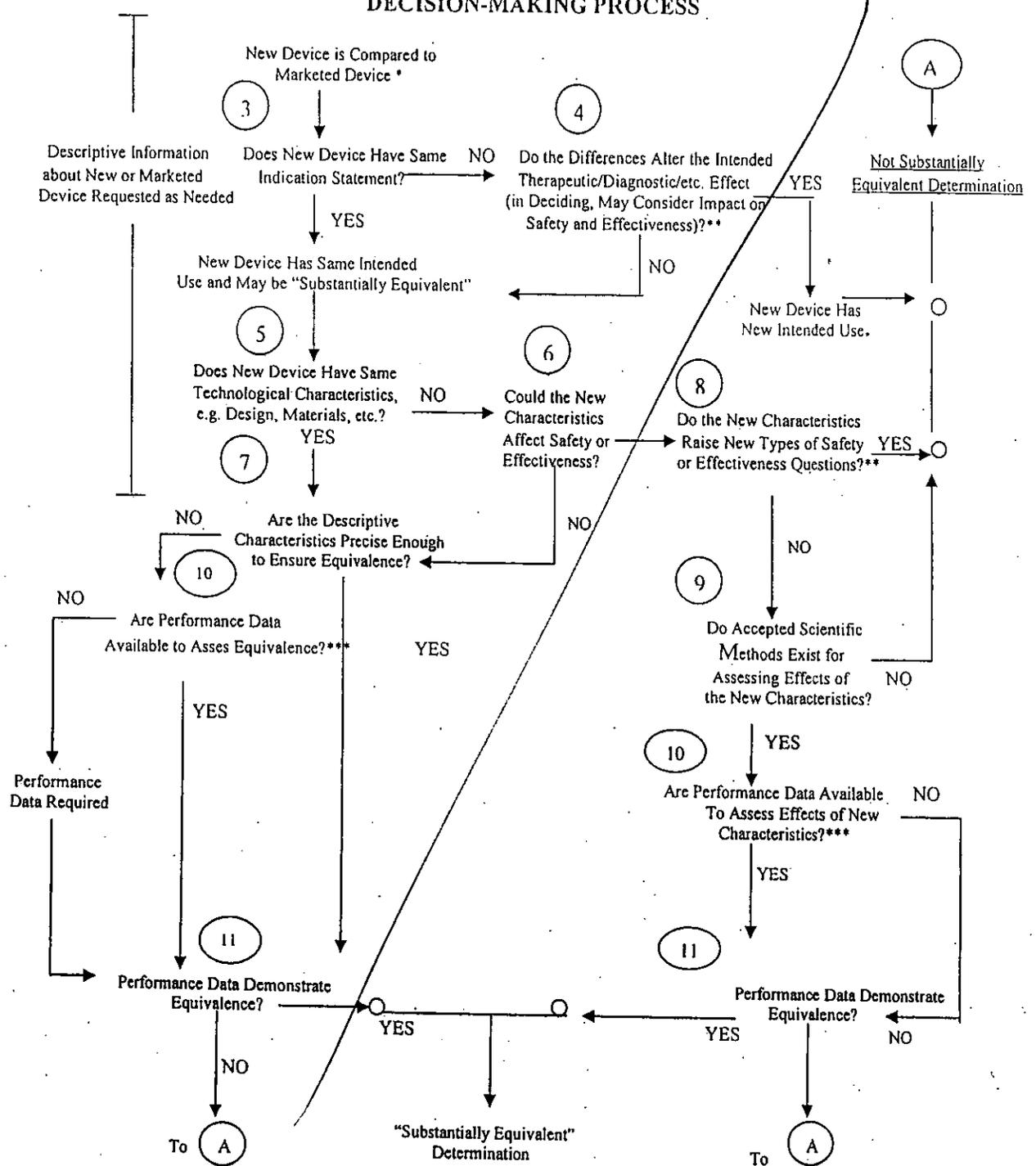
Regulation Number 288,3045 Class* II Product Code MDV
(*If unclassified, see 510(k) Staff)

Additional Product Codes: OIS

Review: [Signature] RETB 6/16/10
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K102722

Date: November 15, 2010

To: The Record

Office: ODE

From: Nadine Y. Sloan, Biomedical Engineer

Division: DGNRD/OSDB

510(k) Holder: Synthes

Device Name: Norian Drillable Inject and Norian Drillable Fast Set Putty

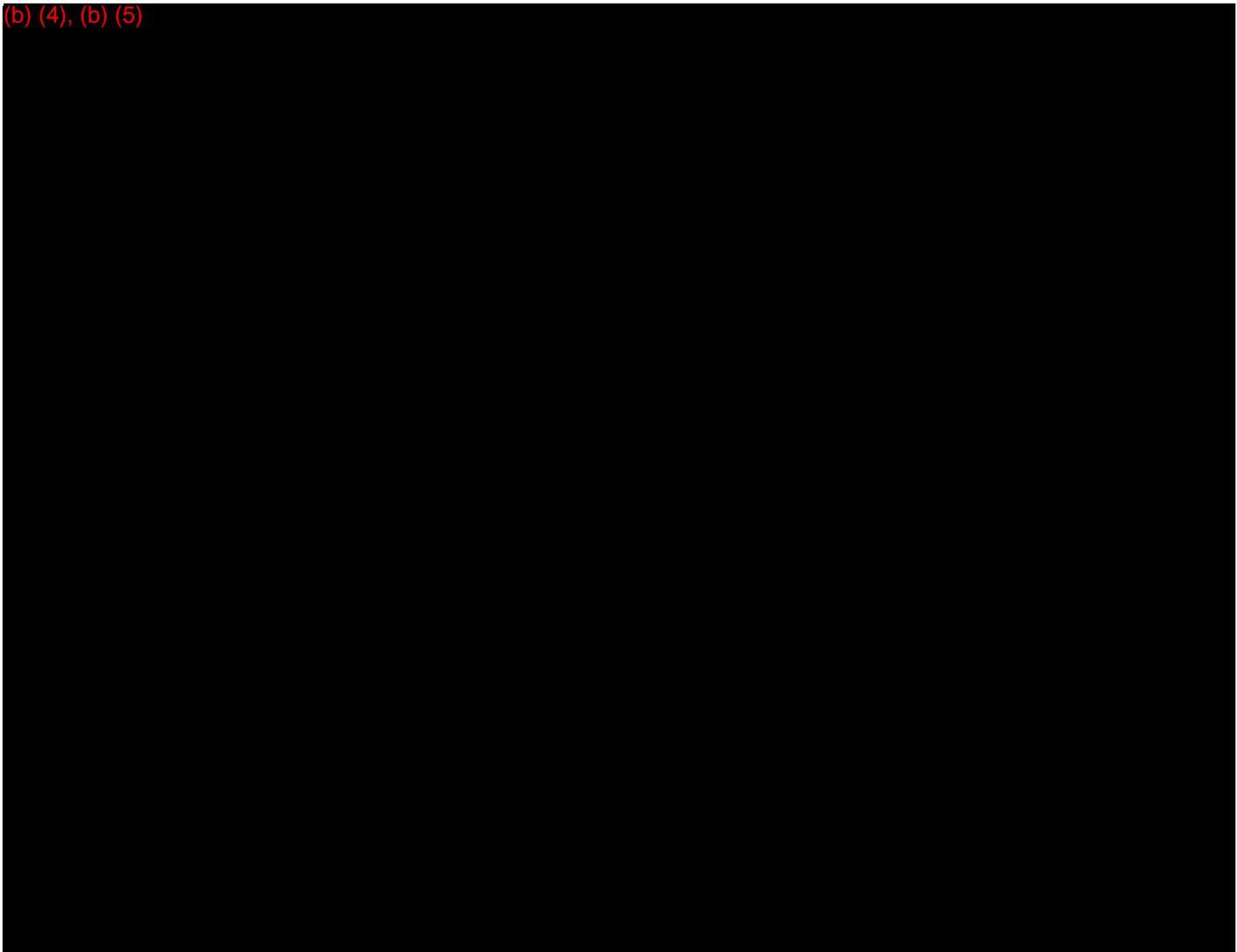
Contact: Jeffrey L. Dow, JD, Director of Clinical and Regulatory Affairs

Phone: 484.356.9720

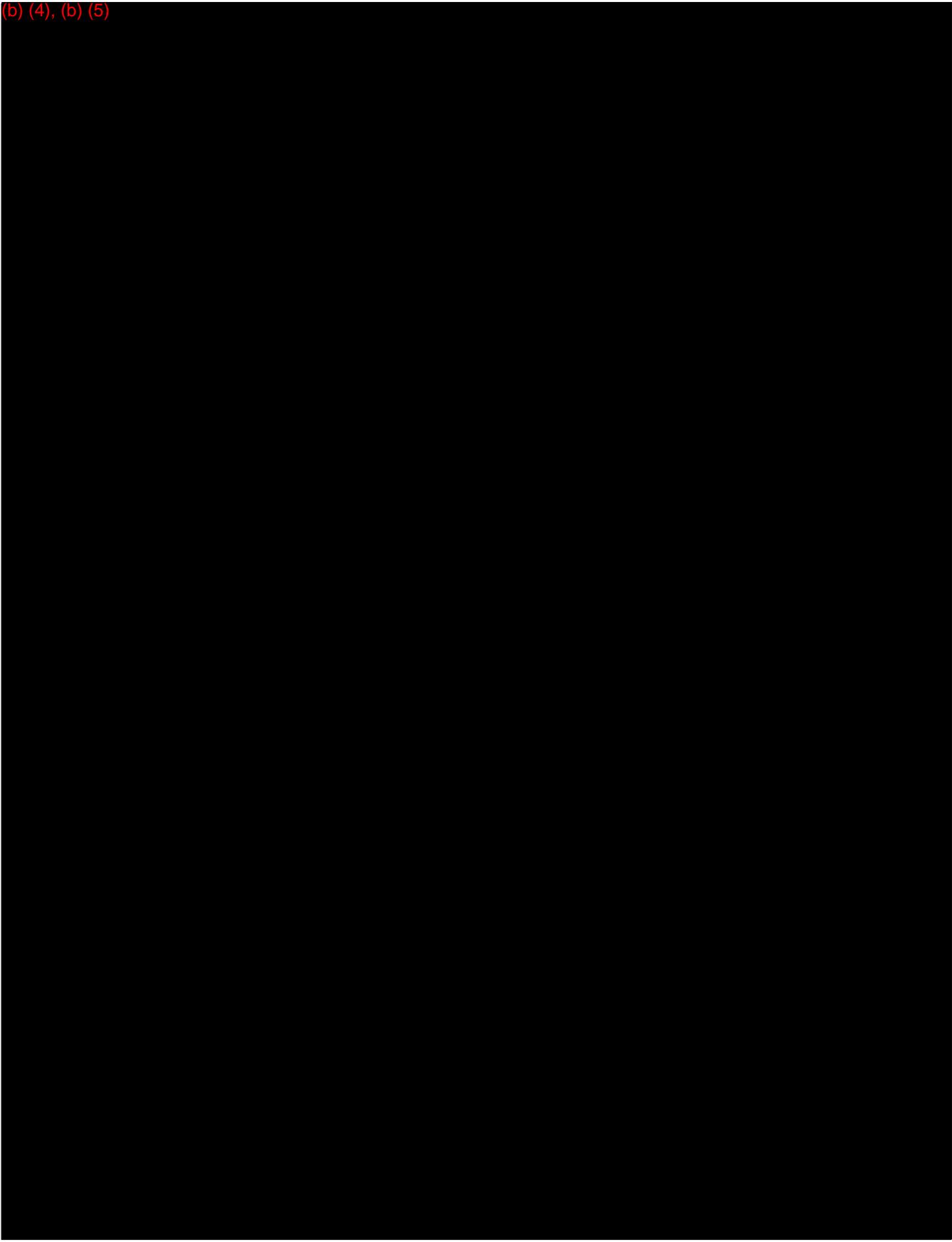
Email: dowj@synthes.com

Recommendation: Additional Information letter

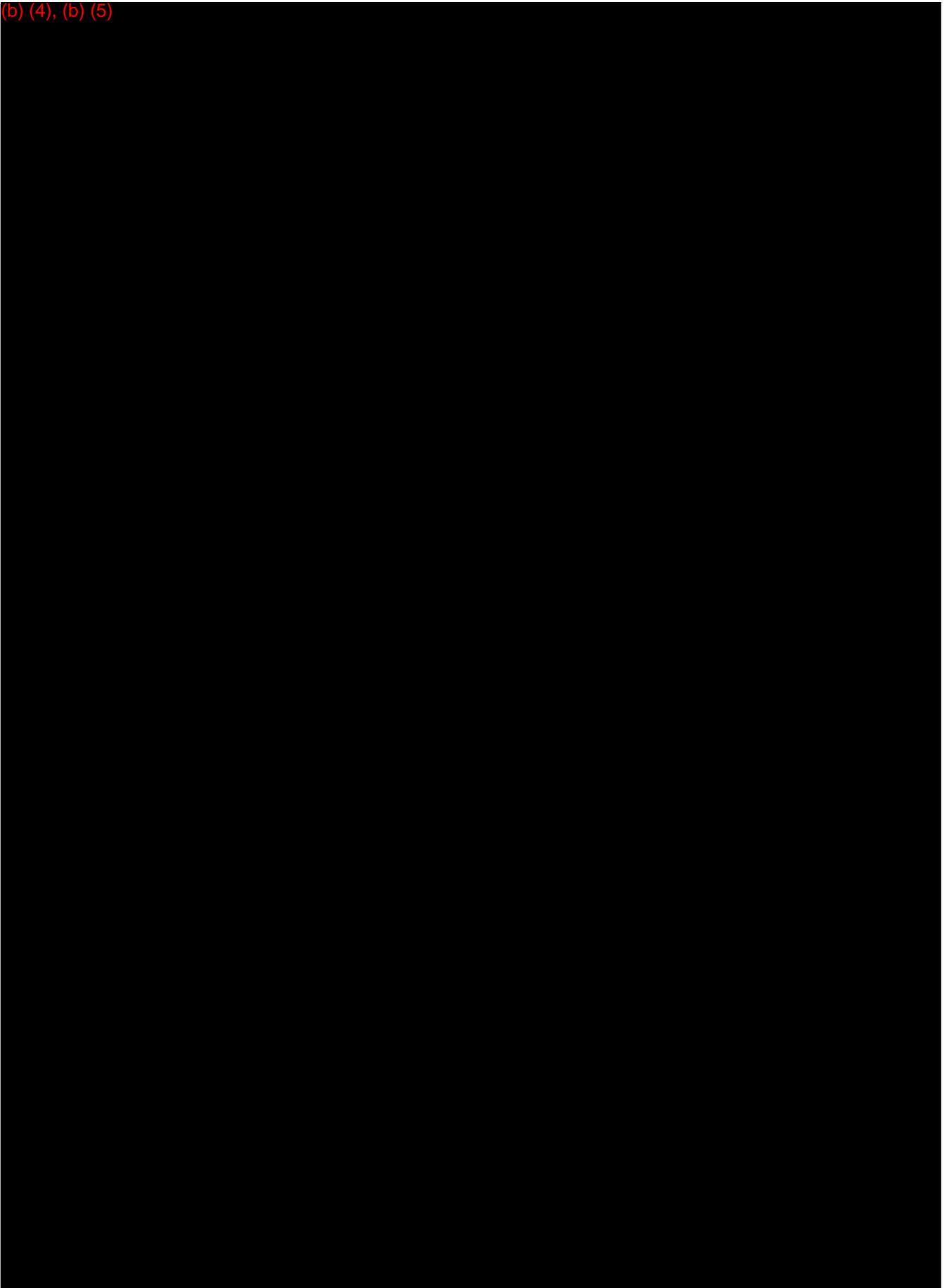
(b) (4), (b) (5)



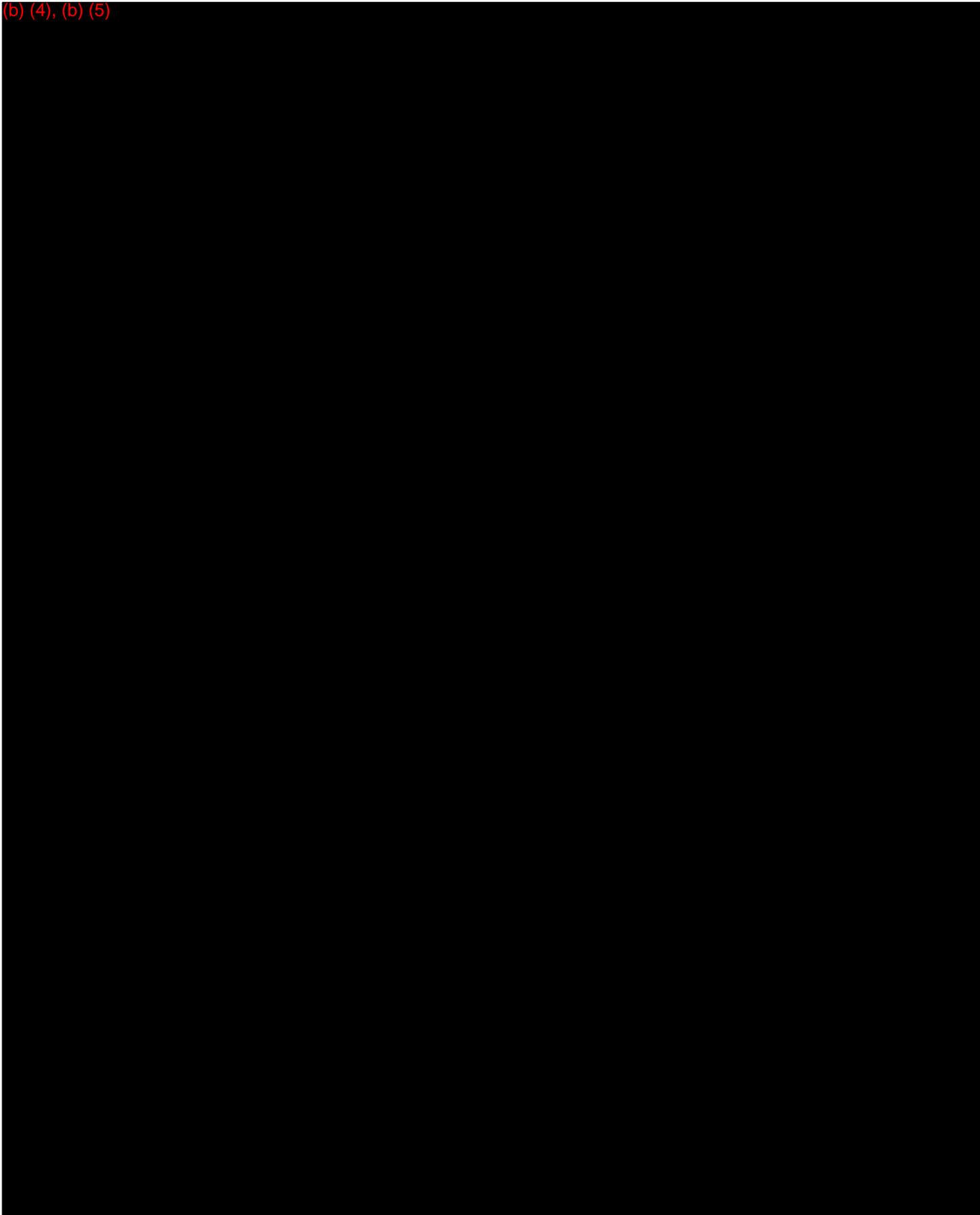
(b) (4), (b) (5)



(b) (4), (b) (5)



(b) (4), (b) (5)



(b) (4), (b) (5)



Reviewer: Radwan S. Khan
Branch Chief: [Signature] **CONOR**

11/16/10
Date

11/16/10
Date

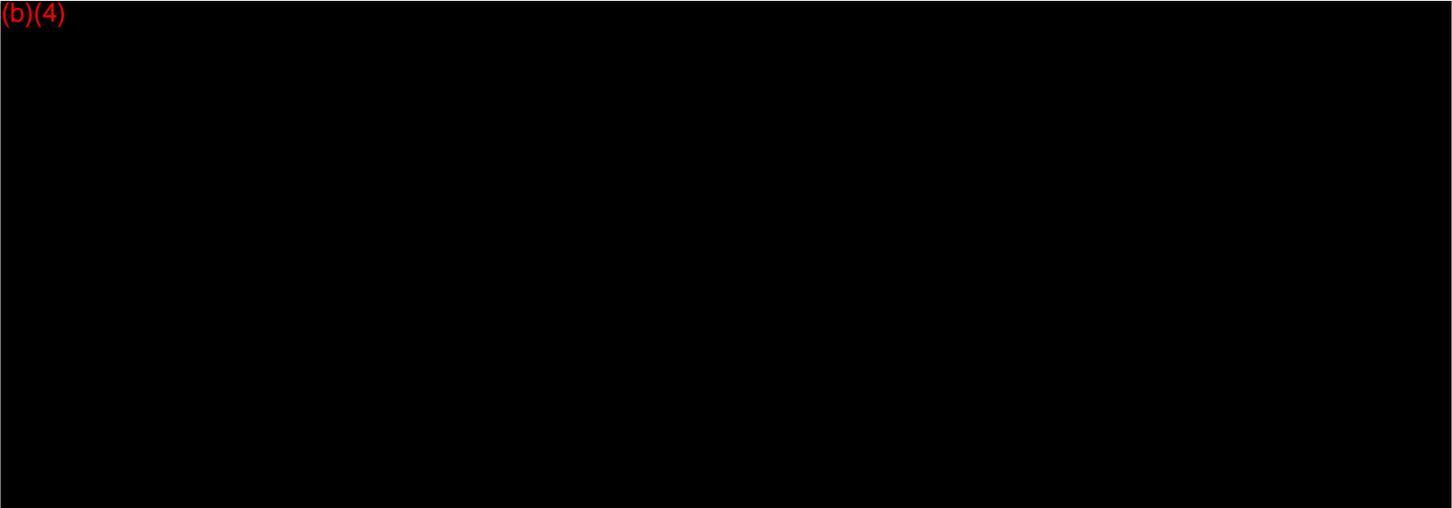
no response from Ms. Dow

Sloan, Nadine Y.

From: Sloan, Nadine Y.
Sent: Monday, October 04, 2010 11:44 AM
To: 'Dow.Jeff@synthes.com'
Subject: RE: Special 510(k)

Dear Jeff,

(b)(4)



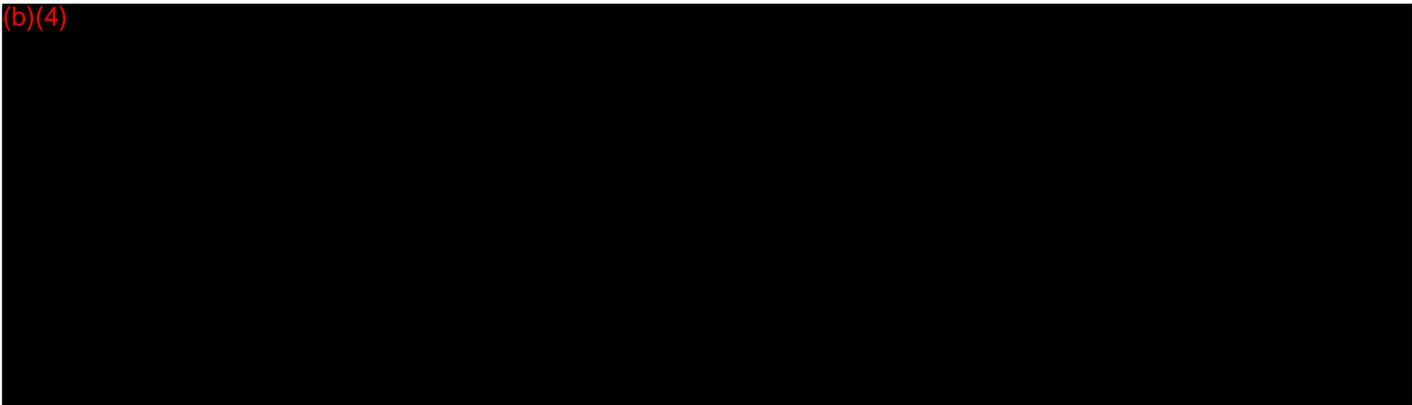
Regards,

Nadine

From: Dow.Jeff@synthes.com [mailto:Dow.Jeff@synthes.com]
Sent: Monday, October 04, 2010 9:38 AM
To: Sloan, Nadine Y.
Cc: Stadtmiller.Allen@synthes.com; Brown.Vernon@synthes.com; Delor.James@synthes.com; Harten.Robert@synthes.com; Fulmer.Mark@synthes.com; Ravitz.James@ARENTFOX.COM
Subject: RE: Special 510(k)

Dear Nadine:

(b)(4)



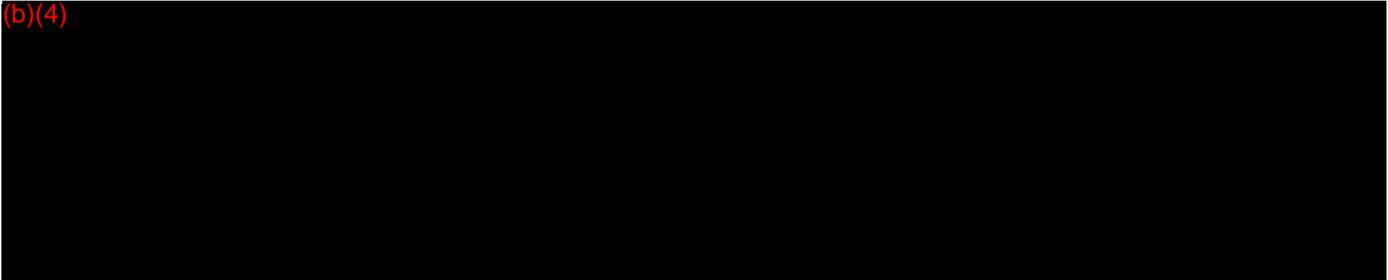
Sincerely,

Jeff

From: Sloan, Nadine Y. [mailto:Nadine.Sloan@fda.hhs.gov]
Sent: Friday, October 01, 2010 3:07 PM
To: Dow, Jeff - United States, West Chester
Subject: Special 510(k)

Dear Mr. Dow,

(b)(4)



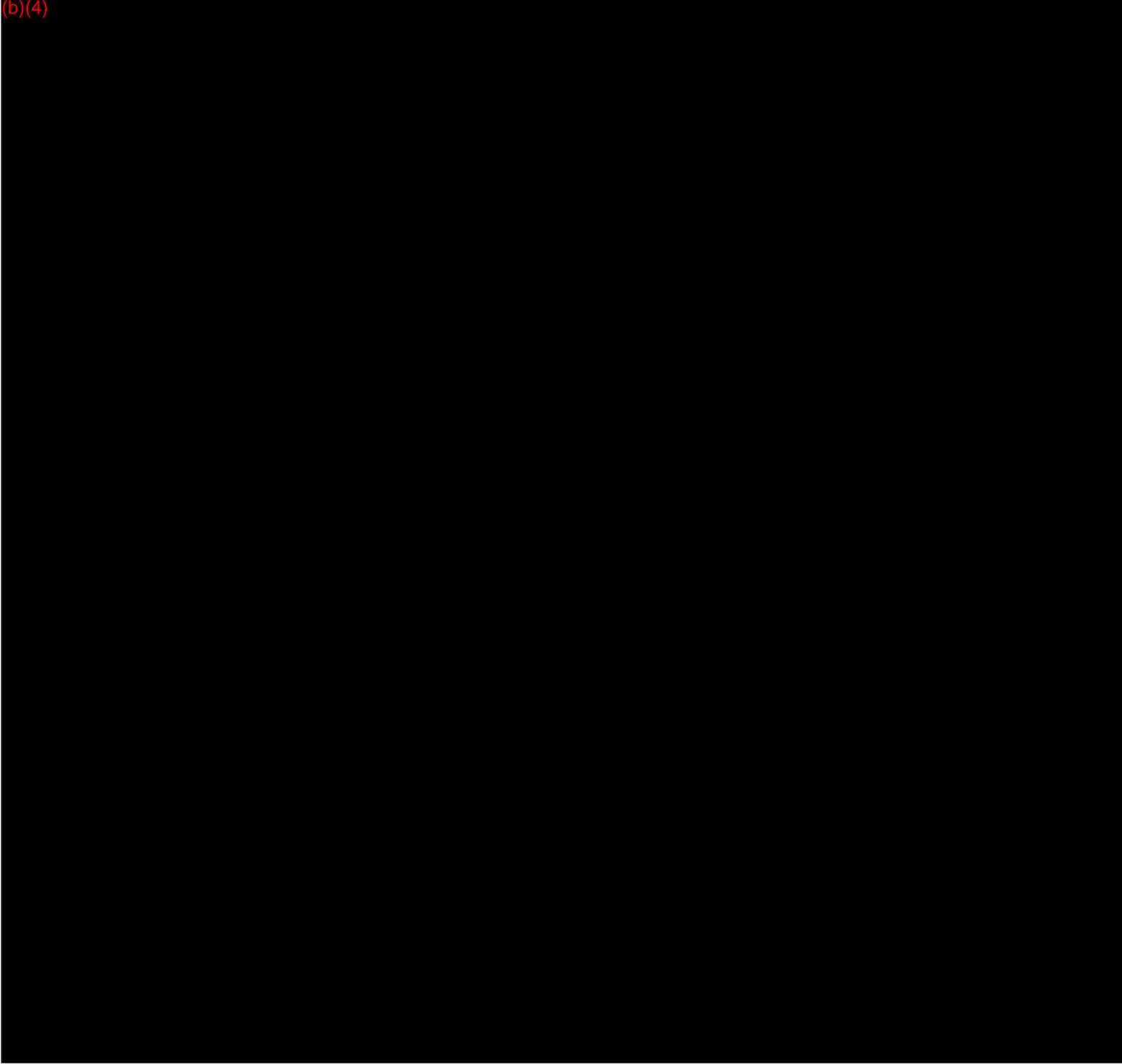
Sincerely,

Nadine

Form for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)

Note: Please send this to the 510k Staff in Word. You do not need anyone to sign this in person.

(b)(4)



Please add this to the file



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center 4 WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

December 17, 2010

SYNTHES USA PRODUCTS LLC
1230 WILSON DRIVE
WEST CHESTER, PENNSYLVANIA 19380
UNITED STATES
ATTN: JEFFREY L. DOW, JD

510k Number: K102722

Product: NORIAN DRILLABLE INJECT, NORIA

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff



Synthes (USA)
1230 Wilson Drive
West Chester, PA 19380

December 13, 2010

Document Mail Center - WO66, Room 0609
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FDA CDRH DMC

K102722/S1

DEC 15 2010

Received

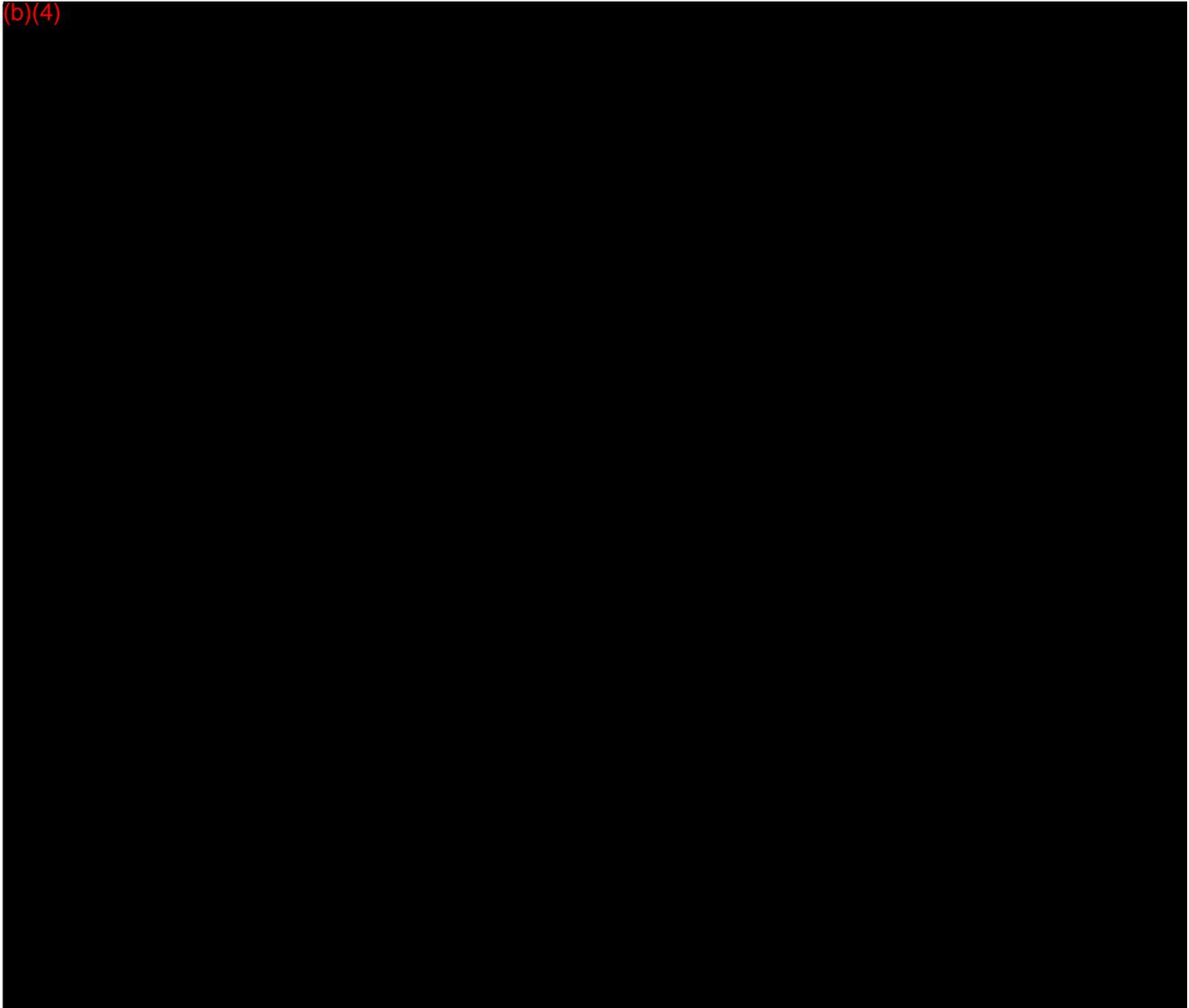
R-47

Attn: Ms. Nadine Sloan

**Re: K102722, Norian Drillable Inject and Norian Drillable Fast Set Putty
Response to AI Letter dated November 16, 2010**

Dear Ms. Sloan:

(b)(4)





Synthes (USA)
1230 Wilson Drive
West Chester, PA 19380

(b)(4)

A large, solid black rectangular redaction box covers the majority of the page's content, starting below the company address and extending nearly to the bottom of the page.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-6
Silver Spring, MD 20993-0002

Synthes (USA)
c/o Mr. Jeffrey L. Dow, JD
Director, Clinical and Regulatory Affairs, Biomaterials
1230 Wilson Drive
West Chester, Pennsylvania 19380

NOV 16 2010

Re: K102722
Device Name: Norian Drillable Inject™ and Norian Drillable Fast Set Putty™
Dated: September 17, 2010
Received: September 21, 2010

Dear Mr. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based on the information you provide. To complete the review of your submission, (b)(4)

(b)(4)

The deficiency identified above represents the issue that we believe needs to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiency, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry

Page 2 - Mr. Jeffrey L. Dow, JD

Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment” at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf>

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Nadine Y. Sloan at (301) 796-6430. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Laurence D. Coyne, Ph.D.
Chief, Restorative Devices Branch
Division of Surgical, Orthopedic and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



INDICATIONS

Norian Drillable Bone Void Filler is 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 can be used as an adjunct to conventional rigid hardware fixation by supporting the bone fragments during the surgical procedure. Once the material has 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 is intended to be placed into bony voids either before or after final fixation.

CONTRAINDICATIONS

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.

Norian Drillable Bone Void Filler should not be used in the presence of active or suspected infection.

Norian Drillable Bone Void Filler is not for screw augmentation.

Norian Drillable Bone Void Filler is not for use in:

- Patients with traumatic open injuries that are predisposed to infection
- Stress bearing applications
- Areas where adjacent bone is avascular, or is incapable of supporting or anchoring the implanted rigid fixation hardware.
- Patients with compromised health (e.g. abnormal calcium metabolism, metabolic bone disease, a recent local untreated infection, vascular or severe neurological disease, infection, immunologic deficiencies or systemic disorders) that result in poor wound healing or will result in tissue deterioration over the implant site.
- Patients who are skeletally immature
- Vertebral compression fractures
- Intra-articular space (i.e., material injected into the joint space).

REF SRS-1000-FRP QTY 1

LOT SETUP

Norian Drillable™

Fast Set Putty™, 10 cc



Material
CST 100400H



INDICATIONS

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- Vertebral compression fractures
- Intra-articular space (i.e., material injected into the joint space).

Qty. 1

SETUP

505-100-FRI

Norian Drillable™

10CE

2011



ISO 13485

10CE



U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center, WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 18, 2011

SYNTHES USA PRODUCTS LLC
1230 WILSON DRIVE
WEST CHESTER, PENNSYLVANIA 19380
UNITED STATES
ATTN: JEFFREY L. DOW, JD

510k Number: K102722

Product: NORIAN DRILLABLE INJECT, NORIA

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff



K102722 / S2

Synthes (USA)
1230 Wilson Drive
West Chester, PA 19380

December 14, 2011

Document Mail Center - WO66, Room 0609
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FDA CDRH DMC

12-23 - JAN 18 2011
Received

Attn: Ms. Nadine Sloan

**Re: K102722, Norian Drillable Inject and Norian Drillable Fast Set Putty
Complete Response to Emails dated January 6, 2011**

Dear Ms. Sloan:

You and I agreed by phone yesterday, January 13, on language that will be added to the cartons and components for Norian Drillable Fast Set Putty and Norian Drillable Inject. This letter is the complete response to your emails dated January 6, 2011 and embodies the agreements we reached yesterday. You have agreed that this response is sufficient to permit CDRH to issue a substantial equivalence clearance letter that will supersede the labeling requirements in the original clearance letter for Norian Drillable, K073303.

Synthes hereby agrees to:

1. Label the outside front panel of every carton containing Norian Drillable Fast Set Putty and Norian Drillable Inject with the whole of the language set forth on page 22 of our original submission of K102722, in boldface 10 point font. This language and placement are illustrated by the photographs accompanying Synthes' December 13, 2010 response to your AI letter of November 16, 2010.
2. Add labels stating "See accompanying Directions for Use for complete indications and contraindications" in boldface type of at least 10 point font to the tray for Norian Drillable Inject and the component pouch for Norian Fast Set Putty as illustrated by the photographs accompanying this response.

If you have any questions concerning this response, please telephone me at 484 467 4174, or contact me by e-mail at dow.jeff@synthes.com. Thank you for your consideration.

Sincerely,

Jeffrey L. Dow, JD

Fast Set Putty

Contains:

- Powder sealed in Mixing Cup
- Spatula



Always use the Fast Set Putty in a clean, dry container. Do not use the putty if the seal is broken or if the powder is clumpy. Do not use the putty if the seal is broken or if the powder is clumpy. Do not use the putty if the seal is broken or if the powder is clumpy.

**See accompanying
Directions-For-Use
for complete indications
and contraindications.**



See the Back and Inside of the Package for complete directions.

100% SIA 2004-100
 100% SIA 2004-100
 100% SIA 2004-100
 100% SIA 2004-100

© 2004

118

SYNTHESES

Solution Syringe

2010110-10

LOT 618 10.015

EXP 2010-10

2010-10

See accompanying
Directions-For-Use
for complete indications
and contraindications.

Calcium Phosphate with Fiber

⚠ Ⓡ Rx

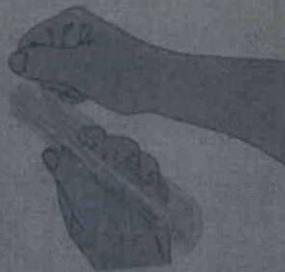
COMPONENTS: STERILE, LINELESS, PACKAGED, OPENED, OR DAMAGED
CONTENTS MAY BE DAMAGED BY TEMPERATURE OR EXCESSIVE HUMIDITY

30-2100-A 2008 J8447-A

1. Open the mixer lid by depressing the thumb latch located at the right corner of the lid. Position the rotary pouch on the rotary mixer by aligning the arrows on the pouch and mixer.



2. Remove the solution syringe from the tray.



3. Using aseptic technique, remove caps from injection port and syringe. Twist the solution syringe securely to the port and fully dispense the solution. Once the solution is injected, complete steps 4-9 immediately.



4. Remove the solution syringe from the injection port. Remove the pouch clip and unfold the rotary pouch with the delivery syringe to the right.

5. Close the lid and depress the thumb latch to lock the lid in place. The mixer is now ready to mix.

6. Depress the Start button to initiate mixing. Mixing is complete after 70 cycles. The "Complete" indicator will flash, and the mixer will beep until the lid is opened.

