

VERTE-STACK® Spinal System
510(k) Summary
January 2007

I. **Company:** Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

MAR 14 2007

Contact: Christine Scifert, M.S., M.E.M.
Group Director, Regulatory Affairs

II. **Proprietary Trade Name:** VERTE-STACK® Spinal System

III. **Classification Name/Product Code:** Spinal Intervertebral Body Fixation Orthosis
(21 CFR 888.3060)

IV. **Product Code:** MQP

V. **Product Description**

The VERTE-STACK® device consists of hemi-cylindrical center cages of various lengths and diameters, as well as hemi-cylindrical add on cages of various lengths, diameters and angulation. The assembled VERTE-STACK® device consists of three components (one hollow center cage, and two hollow add-on cages). The VERTE-STACK® components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The design of the VERTE-STACK® device includes a variety of stackable components of different sizes and heights. The stackable components are designed to suit the individual patient pathology.

The VERTE-STACK® device may be used individually, or two or more may be stacked together in order to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The VERTE-STACK® Spinal System implant components are made of medical grade PEEK-OPTIMA LT1 along with a marker made from either Tantalum or titanium.

Alternatively, VERTE-STACK® Spinal System may be manufactured from titanium alloy.

The VERTE-STACK® Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK® constructs manufactured from PEEK may be used with stainless steel or titanium supplemental

fixation devices. Titanium VERTE-STACK® constructs may not be used with stainless steel supplemental fixation devices.

The purpose of this submission was to modify the geometry of the implants and to include additional sizes into the existing VERTE-STACK® Spinal System.

V. Indications

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System and/or the GDLH® Spinal System. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

VI. Substantial Equivalence

Documentation, including mechanical test results, was provided which demonstrated that the subject VERTE-STACK® Spinal System components are substantially equivalent to the previously cleared VERTE-STACK® Spinal System (K052931, SE 11/13/2005; and K062133, SE 09/26/2006).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert, M.S., M.E.M.
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, TN 38132

MAR 14 2007

Re: K070173
Trade/Device Name: VERTE-STACK[®] Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: February 22, 2007
Received: February 26, 2007

Dear Ms. Scifert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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

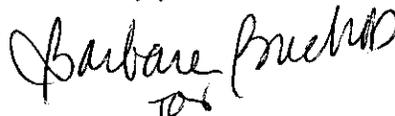
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Christine Scifert, M.S., M.E.M.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a small flourish at the end.

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

Enclosure

January 2007

510(k) Number (if known): K070173

Device Name: VERTE-STACK® Spinal System

Indications for Use:

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System and/or the GDLH® Spinal System. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

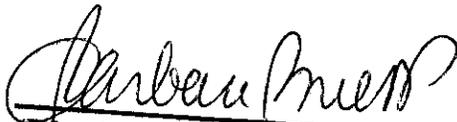
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

510(k) Number K070173



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek
% Ms. Christine Scifert, M.S., M.E.M.
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, TN 38132

MAR 14 2007

Re: K070173
Trade/Device Name: VERTE-STACK® Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: February 22, 2007
Received: February 26, 2007

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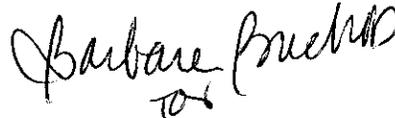
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Sincerely yours,



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

Enclosure

January 2007

510(k) Number (if known): K070173

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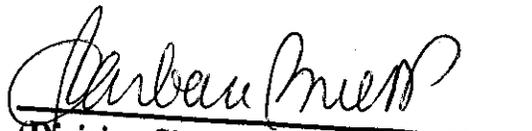
Prescription Use X
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AND/OR

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K070173



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medtronic Sofamor Danek, Inc.
% Ms. Christine Scifert
Group Director, Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

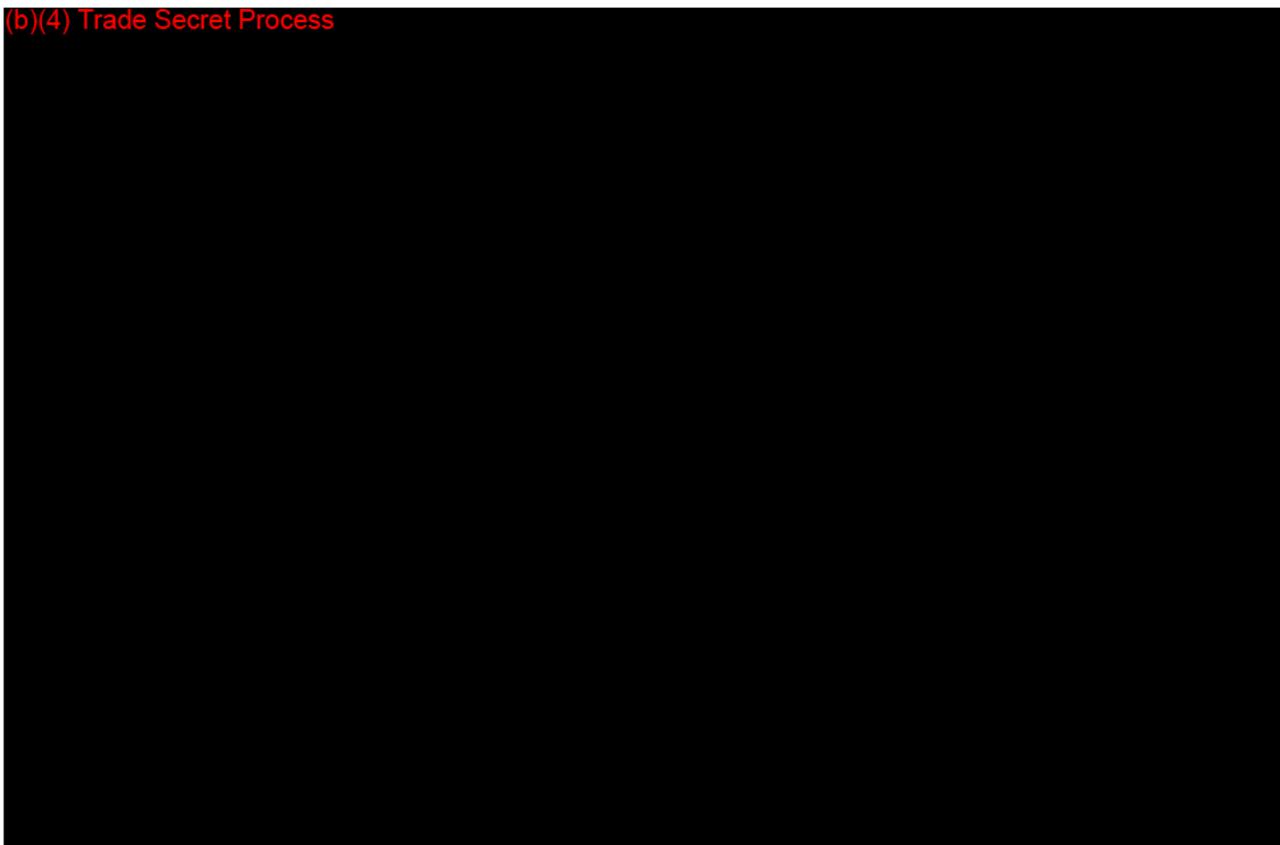
FEB 12 2007

Re: K070173
Trade Name: VERTE-STACK® Spinal System
Dated: January 12, 2007
Received: January 18, 2007

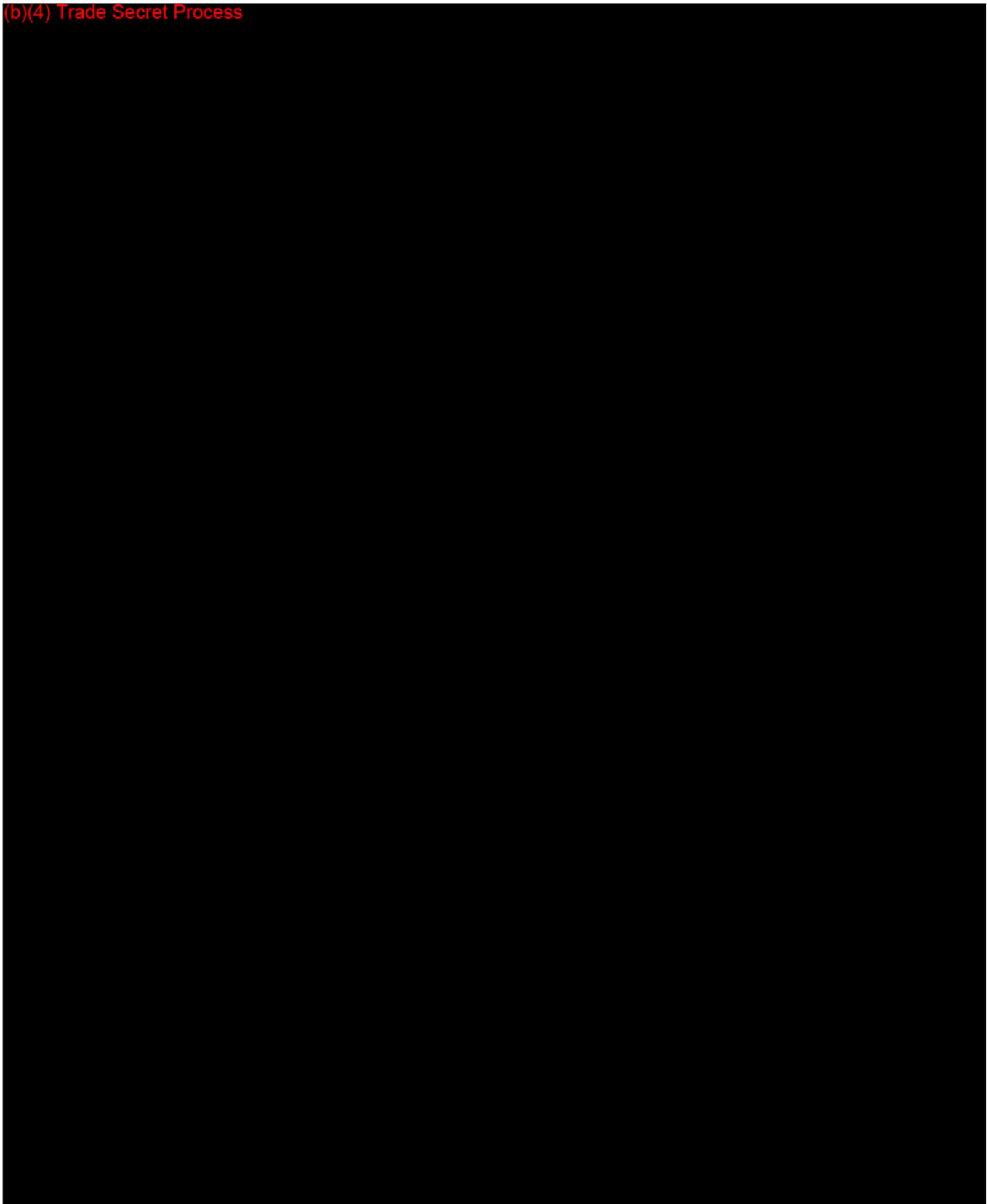
Dear Ms. Scifert:

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 solely on the information you provided. To complete the review of your submission, we require responses to the following items.

(b)(4) Trade Secret Process



(b)(4) Trade Secret Process



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. 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 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. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

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:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Mr. Sergio M. de del Castillo at (240) 276-3751. 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 (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


for Mark N. Melkerson

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
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FEB 12 2007

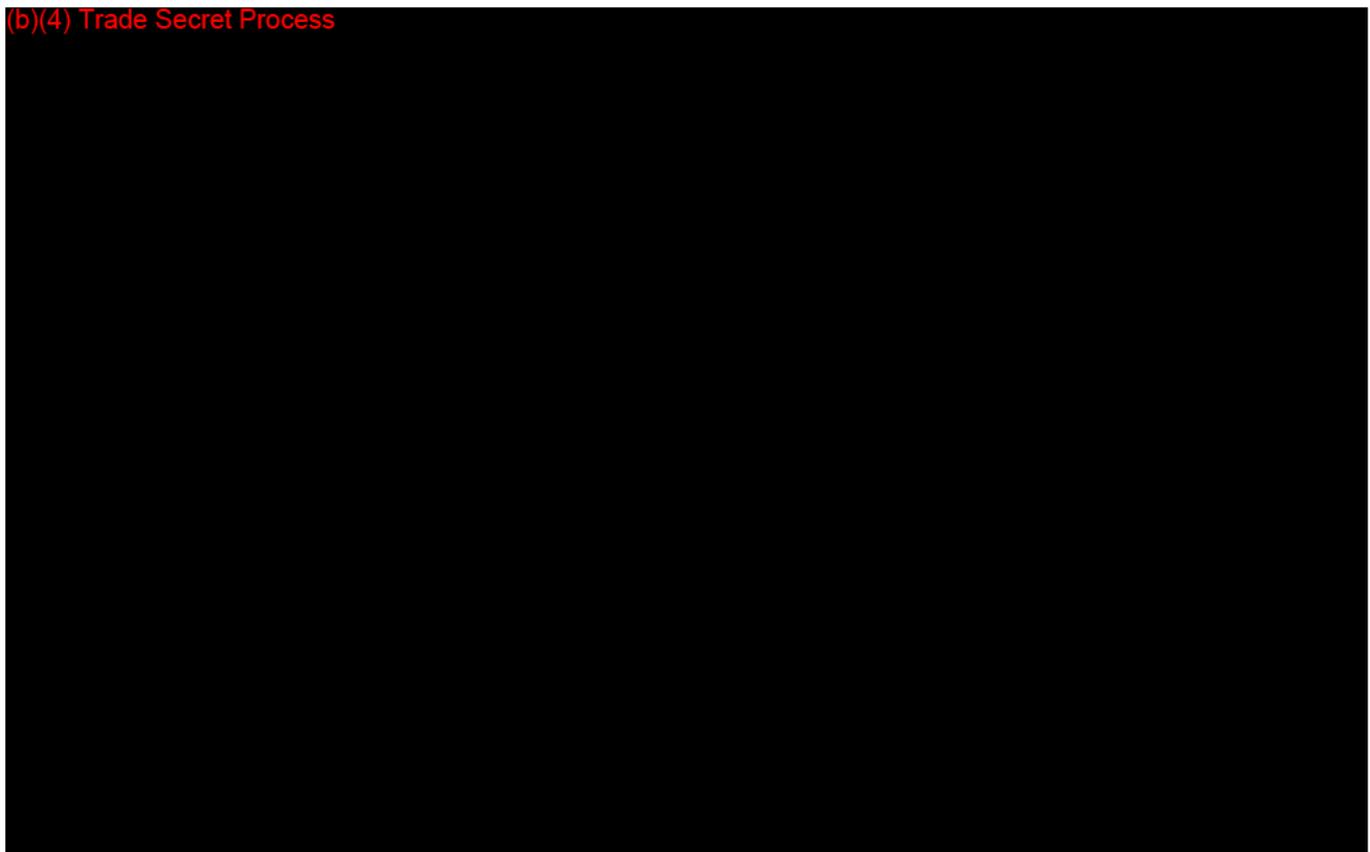
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% Ms. Christine Scifert
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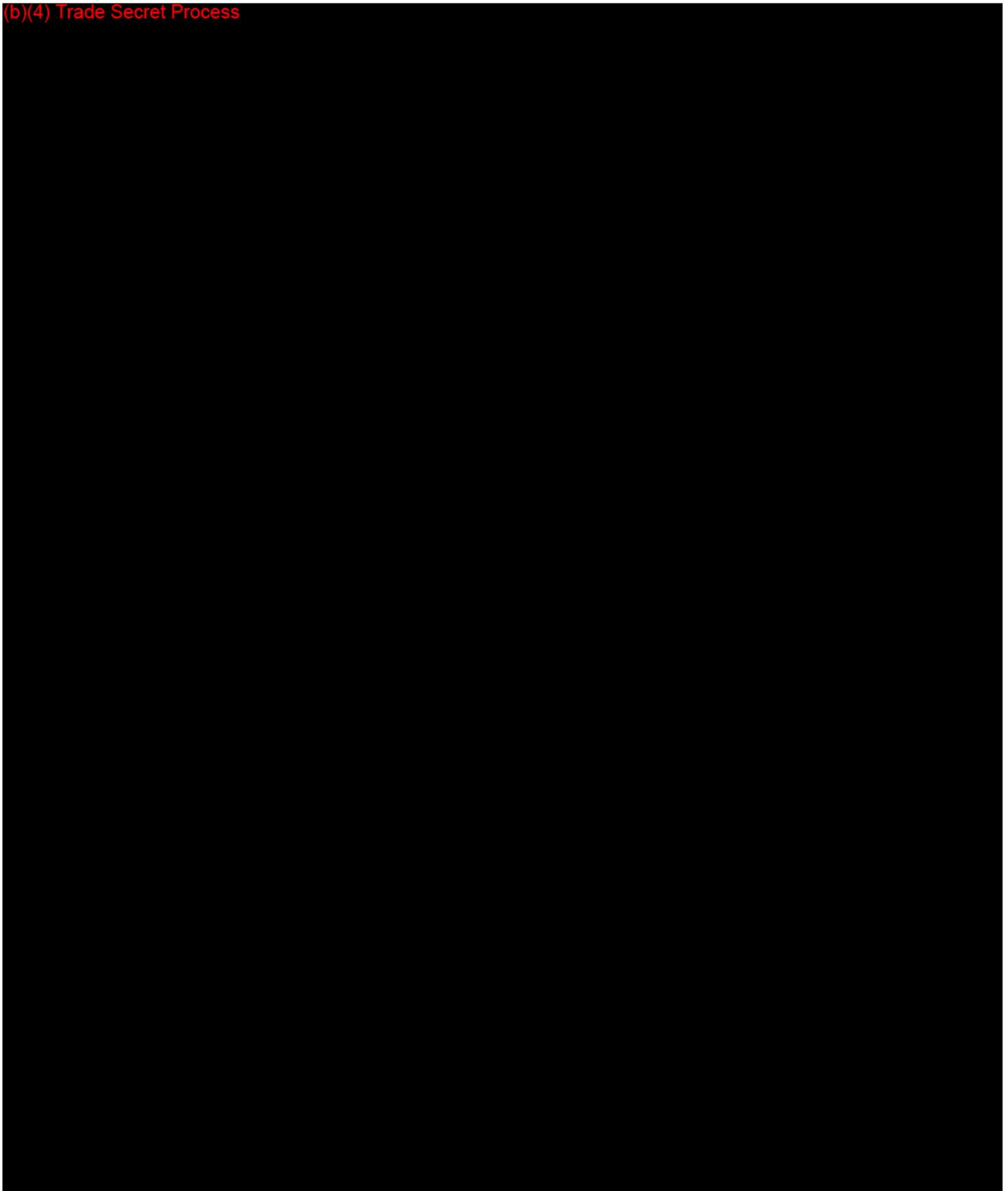
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 3 – Ms. Christine Scifert

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Sincerely yours,



Mark N. Melkerson
 Director
 Division of General, Restorative
 and Neurological Devices

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-410	de del Castillo	2/9/07				Office of Device Evaluation		
k-110	Stevens	2/9/07				Center for Devices and Radiological Health		

Page 4 – Ms. Christine Scifert

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.
f/t:SMC:jbg:02-07-07

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 19, 2007

MEDTRONIC SOFAMOR DANEK, INC.
1800 PYRAMID PL.
MEMPHIS, TN 38132
ATTN: CHRISTINE SCIFERT

510(k) Number: K070173
Received: 18-JAN-2007
Product: VERTE-STACK SPINAL
SYSTEM

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) (HFZ-401) 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.

Please note the following documents as they relate to 510(k) review:
1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". 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 (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3) 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 www.fda.gov/cdrh/ode/a02-01.html.

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 www.fda.gov/cdrh/elecsb.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health



K070173

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Write the Payment Identification number on your check.	
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
<ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)		2. CONTACT NAME	
MEDTRONIC SOFAMOR DANEK 1800 PYRAMID PLACE MEMPHIS TN 38132 US		Christine Scifert	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)		2.1 E-MAIL ADDRESS	
(b)(4)		christine.scifert@medtronic.com	
		2.2 TELEPHONE NUMBER (include Area code)	
		901-344-1538	
		2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
		901-346-9738	
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/dc/mdufma)			
Select an application type:		3.1 Select one of the types below	
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party		<input checked="" type="checkbox"/> Original Application	
<input type="checkbox"/> Biologics License Application (BLA)		Supplement Types:	
<input type="checkbox"/> Premarket Approval Application (PMA)		<input type="checkbox"/> Efficacy (BLA)	
<input type="checkbox"/> Modular PMA		<input type="checkbox"/> Panel Track (PMA, PMR, PDP)	
<input type="checkbox"/> Product Development Protocol (PDP)		<input type="checkbox"/> Real-Time (PMA, PMR, PDP)	
<input type="checkbox"/> Premarket Report (PMR)		<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. 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, parents, and partner firms		<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	
6. 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	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)			
(b)(4)		02-Jan-2007	

OK
IT

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
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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 Medtronic Sofamor Danek	Establishment Registration Number (if known) 1030489		
Division Name (if applicable)	Phone Number (including area code) (901) 396-3133		
Street Address 1800 Pyramid Place	FAX Number (including area code) (901) 346-9738		
City Memphis	State / Province TN	ZIP/Postal Code 38132	Country USA
Contact Name Christine Scifert			
Contact Title Group Director, Regulatory Affairs		Contact E-mail Address christine.scifert@medtronic.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/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1**REASON FOR APPLICATION - PMA, PDP, OR HDE**

- Withdrawal
- Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

- Change in design, component, or specification:
 - Software / Hardware
 - Color Additive
 - Material
 - Specifications
 - Other (specify below)

- Location change:
 - Manufacturer
 - Sterilizer
 - Packager

- Process change:
 - Manufacturing
 - Sterilization
 - Packaging
 - Other (specify below)

- Labeling change:
 - Indications
 - Instructions
 - Performance
 - Shelf Life
 - Trade Name
 - Other (specify below)

- Report Submission:
 - Annual or Periodic
 - Post-approval Study
 - Adverse Reaction
 - Device Defect
 - Amendment

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

- Other Reason (specify):

SECTION D2**REASON FOR APPLICATION - IDE**

- New Device
- New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
 - Correspondent / Applicant
 - Design / Device
 - Informed Consent
 - Manufacturer
 - Manufacturing Process
 - Protocol - Feasibility
 - Protocol - Other
 - Sponsor

- Report submission:
 - Current Investigator
 - Annual Progress Report
 - Site Waiver Report
 - Final

- Repose to FDA Letter Concerning:
 - Conditional Approval
 - Deemed Approved
 - Deficient Final Report
 - Deficient Progress Report
 - Deficient Investigator Report
 - Disapproval
 - Request Extension of Time to Respond to FDA
 - Request Meeting
 - Request Hearing

- Other Reason (specify):

SECTION D3**REASON FOR SUBMISSION - 510(k)**

- New Device

- Additional or Expanded Indications

- Change in Technology

- Other Reason (specify):
Additional components added to system. Minor modifications to some of the existing parts

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	MQP	2	3	4	
5		6	7	8	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K052931	1	VERTE-STACK® Spinal System	1	Medtronic Sofamor Danek
2	K062133	1	VERTE-STACK® Spinal System	1	Medtronic Sofamor Danek
3		2		2	
4		4		4	
5		5		5	
6		6		6	

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Interlaminar Fixation Orthosis

	Trade or Proprietary or Model Name for This Device		Model Number
1	VERTE-STACK® Spinal System	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
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 MQP	C.F.R. Section (if applicable) 888.3060	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General, Restorative and Neurological Device		

Indications (from labeling)

Please see attached indications sheet

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 3003006544	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Medtronic Sofamor Danek Deggendorf		Establishment Registration Number 3003006544	
Division Name (if applicable) Deggendorf Manufacturing		Phone Number (including area code) ()	
Street Address WerfstraBe 17		FAX Number (including area code) ()	
City Deggendorf		State / Province	ZIP/Postal Code Country GmbH
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 1824199	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Warsaw Orthopedic, Inc.		Establishment Registration Number 1824199	
Division Name (if applicable) Medtronic Sofamor Danek Manufacturing, Inc.		Phone Number (including area code) (219) 267-6826	
Street Address 2500 Silveus Crossing		FAX Number (including area code) ()	
City Warsaw		State / Province IN	ZIP/Postal Code 46582 Country USA
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 2647346	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Medtronic Puerto Rico Operations Co.		Establishment Registration Number 2647346	
Division Name (if applicable) Puerto Rico Manufacturing		Phone Number (including area code) (787) 656-0276	
Street Address Road 909, Km4 Barrio Mariana		FAX Number (including area code) ()	
City Humacao		State / Province	ZIP/Postal Code 00792 Country PR
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:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

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

VERTE-STACK® Spinal System
Special 510(k) Application
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Medtronic

SOFAMOR DANEK

Regulatory Affairs Department

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Memphis, TN 38132
www.medtronic.com

tel 901.396.3133
fax 901.346.9738
tel 800.876.3133

January 12, 2007

FDA CDRH DMC

JAN 18 2007

RECEIVED

Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mailing Center (HFZ-401)
9200 Corporate Blvd., Room 20N
Rockville, Maryland 20850

Re: Special 510(k): VERTE-STACK® Spinal System
Medical Specialty: General and Restorative and Neurological Device
Legally Marketed Device: VERTE-STACK® Spinal System (K052931 and K062133)

Dear Document Control Clerk:

The purpose of this **Special 510(k)** is to offer a slightly modified version of the VERTE-STACK® Spinal System components previously cleared by the FDA. From a regulatory point of view, we regard this device to be substantially equivalent¹ to itself.

Background:

The VERTE-STACK® device consists of hemi-cylindrical center struts of various widths, depths, and heights, as well as hemi-cylindrical end caps of various widths, depths, heights, and angulations. The assembled VERTE-STACK® device consists of three components (one hollow center strut, and two hollow end caps). The VERTE-STACK® components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The design of the VERTE-STACK® device includes a variety of stackable components of different sizes and heights. The stackable components are designed to suit the individual patient anatomy. The device may be used individually or stacked together in order to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy. The VERTE-STACK® Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability.

¹ "The term 'substantially equivalent' as used herein is intended to be a determination of substantial equivalency under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits or other patent matters." (*Federal Register*, Vol. 42, No. 163, Aug. 23, 1977, page 42525 and 42529).

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Previously cleared VERTE-STACK® Spinal System implant components are manufactured from either medical grade PEEK-OPTIMA LT1 described by ASTM Standard F2026, or medical grade titanium alloy as described by the voluntary standard ASTM F-136 or ISO 5832-2. The Tantalum marker used in the PEEK version of this product is made to the voluntary standard of ASTM F-560. The subject components will only be manufactured from PEEK-OPTIMA LT1 and contain Tantalum markers.

The VERTE-STACK® Spinal System was originally cleared by the FDA in K021791 (SE 08/23/02) as a non-sterile device. A gamma-sterilized version of the VERTE-STACK® product was subsequently cleared by the FDA in K023570 (SE 11/19/02). Several modifications to the system have since been made. The subject VERTE-STACK® ANATOMIC PEEK™ components represent minor modifications to the VERTE-STACK® Spinal System components previously cleared in K052931 (SE 11/13/2005) and in K062133 (SE 09/26/06).

The subject components are being offered in a slightly modified design, however, all other aspects of the subject device including intended use, indications of use, and supplemental fixation devices used with these components are identical to the predicate device. The fundamental scientific technology will remain unchanged.

(b)(4) Trade Secret Process



This application is being submitted in accordance with the CDRH's final guidance on the "New 510(k) Paradigm; Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications."

We conducted a risk analysis and the necessary verification and validation activities and have determined that the design outputs of the modified device meet the design input requirements. In **Attachment 1** we provide a Summary of Design Control Activities meeting the "Special 510(k) Device Modification" requirements. The proposed modifications do not affect the device's intended use or alter the device's fundamental scientific technology.

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21 CFR 807.87

The following are the basic requirements given in 21 CFR 807.87, all of which are found in the original 510(k)s for our cleared device. Refer to K052931 and K062133 for additional product details and further information regarding this device.

- (a) Device Name
Common or Usual Name: Bone Fixation Appliance
Proposed Proprietary or Trade Name: VERTE-STACK® Spinal System
- (b) Manufacturing Facility
Medtronic Sofamor Danek Deggendorf
WerfstraBe 17
Deggendorf, GmBh
- Warsaw Orthopedic, Inc. (also known as)
Medtronic Sofamor Danek Manufacturing, Inc.
2500 Silveus Crossing
Warsaw, Indiana 46582
Telephone: 219-267-6826
- Medtronic Puerto Rico Operations, Co (also known as)
Puerto Rico Manufacturing
Road 909, Km. 4
Barrio Mariana
Humacao, Puerto Rico 00792
Telephone: 787-656-0276
- (c) Establishment Registration Number
1030489-Medtronic Sofamor Danek Inc., USA
3003006544-Medtronic Sofamor Danek Deggendorf
1824199-Warsaw Orthopedic (also known as Medtronic Sofamor Danek Manufacturing, Inc.)
2647346-Medtronic Puerto Rico Operations, Co (also known as Puerto Rico Manufacturing)
- (d) Classification/Product Code
Class II/21 CFR 888.3060/MQP
- (e) Performance Standards: We are unaware of any performance standards for this product presently. The material used to make the Special 510(k) items described in this submission will be PEEK-OPTIMA LT1 described by ASTM Standard F2026. The tantalum markers used for this product is made to the voluntary standard of ASTM F-560.
- (f) Labeling: A sample label is provided in **Attachment 3** of this submission. A draft package insert is provided in **Attachment 4** of this submission. This insert is identical to that provided in the previously cleared submission K062427. "The electronic labeling

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provision (Section 206) in the recently enacted MDUFMA law (Medical Device User Fee and Modernization Act of 2002) says:

Section 502(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(f)) is amended by adding at the end the following: 'Required labeling for prescription devices intended for use in health care facilities may be made available solely by electronic means provided that the labeling complies with all applicable requirements of law and, that the manufacturer affords health care facilities the opportunity to request the labeling in paper form, and after such request, promptly provides the health care facility the requested information without additional cost.'

Therefore, MSD reserves the right at a later date not to include a hard copy of a package insert such as shown in **Attachment 4** with every component described in this 510(k), but rather to instead include multiple language versions of sentences similar to: 'For the latest important medical information about this system including indications, contraindications, warnings, and precautions, use the internet to see an electronic version of this labeling information by going to www.xxxxxxxxxxx. If a copy of this labeling is needed in paper form, please contact the company at _____ or call _____ and a hard copy will be provided promptly without additional cost.'

- (g) Statement of Similarities and Differences: The VERTE-STACK® Spinal System components included in this submission are substantially equivalent to those previously cleared in K052931 and K062133. There have been no changes to the indications of use. The fundamental scientific technology of the system, to stabilize the spine as an aid to fusion, has not changed.

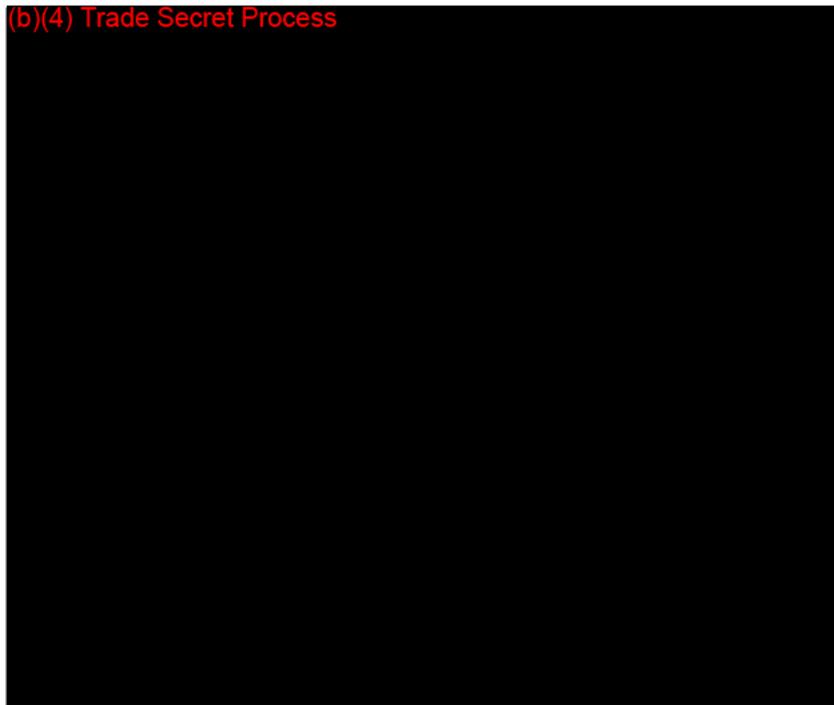
(b)(4) Trade Secret Process
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted] To confirm that the above changes did not

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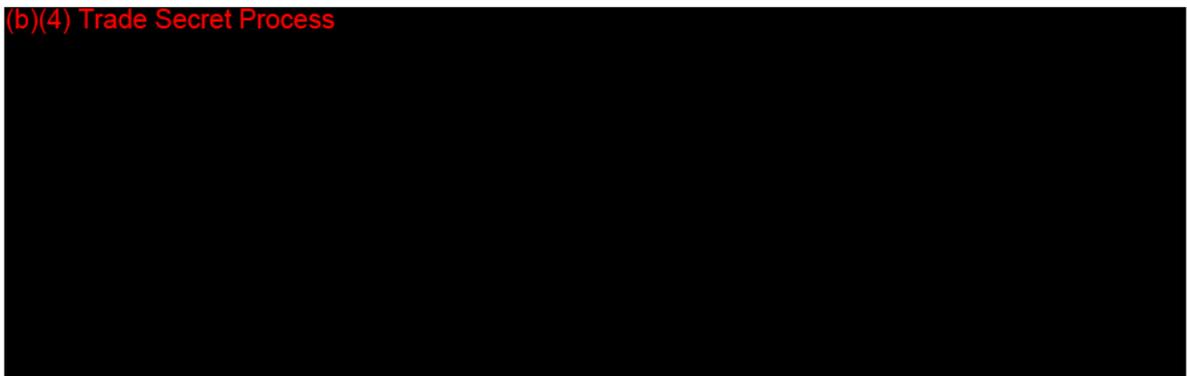
introduce a new worst case, mechanical testing of these devices was performed. These results are summarized here and are further discussed in the risk analysis and mechanical testing section found in **Attachment 1 and Attachment 2** of this submission.

Table 1 Predicate and Subject VERTE-STACK® Device Test Results

(b)(4) Trade Secret Process

A large black rectangular redaction box covers the content of Table 1. The text "(b)(4) Trade Secret Process" is written in red at the top left corner of the redacted area.

(b)(4) Trade Secret Process

A large black rectangular redaction box covers the content of Table 2. The text "(b)(4) Trade Secret Process" is written in red at the top left corner of the redacted area.

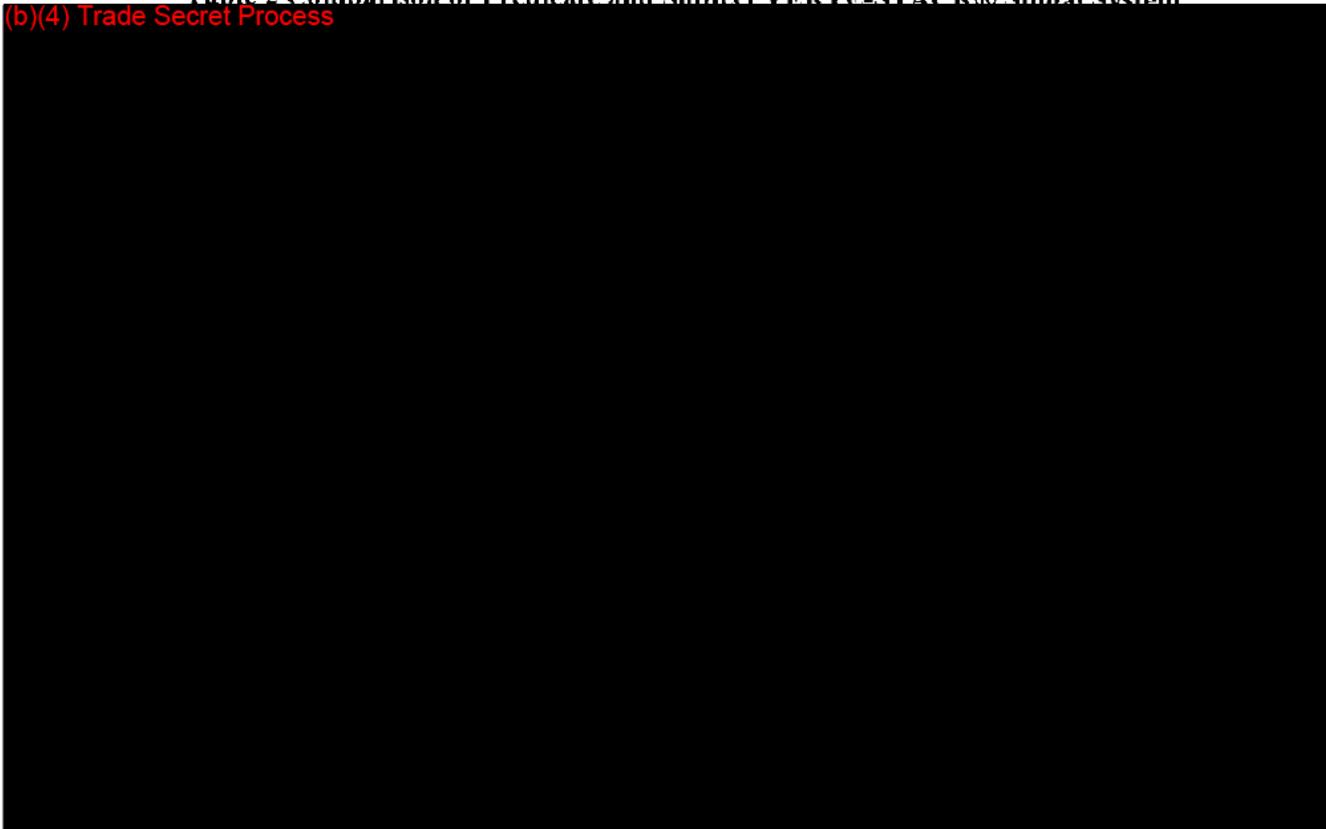
A comparison of the predicate and subject similarities and differences can be seen in **Table 2** below. As evidenced by the comparison table, the subject device is similar to the predicate device in terms of height, width, depth, intended use and use with supplemental fixation.

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Table 2 Comparison of Predicate and Subject VERTE-STACK® Spinal System

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- (h) Safety and Effectiveness
The VERTE-STACK® Spinal System components included in this submission are substantially equivalent to those previously cleared in K052931 and K062133. A Summary of Design Control Activities required for a Special 510(k) is provided in **Attachment 1**. A complete Risk Analysis is also provided in **Attachment 1** of this submission.
- (i) 510(k) Summary
A 510(k) summary for FDA distribution upon request is provided in **Attachment 5**.
- (j) Substantial Equivalence
The data presented within this submission demonstrates that the subject components are substantially equivalent to the predicate VERTE-STACK® Spinal System device, itself, a Class II device.

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(k) Truthful and Accurate Statement

A Truthful and Accurate Statement is attached to the end of this cover letter.

(l) Product Numbers/Engineering Drawings

A complete listing of the new VERTE-STACK® Spinal System components is provided in **Attachment 6** of this submission. The previously cleared VERTE-STACK® components appear in regular text while the subject components are noted in **bold** text. Also included in this submission is a listing of instruments that may be used with the VERTE-STACK® Spinal System. These instruments are considered Class I manual instruments and are thus exempt, and are only included in this submission for the sake of completeness. Drawings of the subject VERTE-STACK® Spinal System components are provided in **Attachment 7** of this submission.

Indications Statement

In compliance with the form required after January 1, 1996, **Attachment 8** contains the indications for this device.

Confidentiality of Information

The enclosed materials and descriptions contain information, which is trade secret or confidential under 21 CFR 20.61 and not disclosable to the public under the Freedom of Information Act (FOIA). If you are unable to assure us that the enclosed information will not be disclosed to the public, we request that this submission be handled by FDA in accordance with 21 CFR 20.44 relating to presubmission reviews. Consequently, until you hear otherwise from us, we ask that you keep our application for this device confidential. We consider this premarket notification confidential commercial information. If we disclose this application to anyone except consultants or employees, we will notify FDA.

As per the "New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, Final Guidance," we anticipate that the Office of Device Evaluation will provide us with a response to this Special 510(k)s within 30 days of receipt by the Document Mail Center. Notification of clearance of this 510(k), or requests for further information may be sent to Medtronic Sofamor Danek by fax to me at (901) 346-9738.

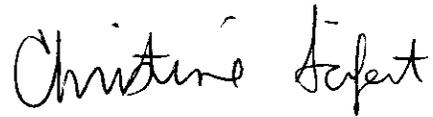
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If you have any questions regarding this submission, please call Raphael McInnis or me at (901) 396-3133. You may also email questions to Raphael McInnis at raphael.mcinnis@medtronic.com or to me at christine.scifert@medtronic.com.

Sincerely,

A handwritten signature in black ink that reads "Christine Scifert". The signature is written in a cursive style with a large initial 'C' and 'S'.

Christine Scifert, M.S., M.E.M.,
Group Director, Regulatory Affairs
Attachments

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Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Group Director of Regulatory Affairs, at Medtronic Sofamor Danek, I believe to the best of my knowledge, all data and information submitted in this premarket notification is truthful and accurate and that no material fact has been omitted.

<u>Christine Scifert</u>	<u>1/12/07</u>
Christine Scifert, M.S., M.E.M.,	Date
Group Director, Regulatory Affairs	

*(Premarket Notification [510(k)] Number

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Attachment 1

Summary of Design Controls/Risk Analysis

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Summary of Design Control Activities for the modified components of the VERTE-STACK® Spinal System

In this summary, we provide appropriate supporting data of design control activities within the meaning of §807.87(g). This summary includes the following:

- An identification of the Risk Analysis methods used to assess the impact of the modification on the device and its components as well as the results of the analysis:

A Failure Mode and Effects Analysis was performed to identify possible hazards associated with the modified features of the VERTE-STACK® Spinal System. A summary of this analysis is included in this Summary of Design Control Activities.

- An identification, based on the Risk Analysis, of the verification and/or validation activities performed, including methods or tests used and the acceptance criteria applied

Based on the possible hazards identified in the Failure Mode and Effects Analysis, design verification was performed. A summary of this Design Verification is included in this Summary of Design Control and identifies the particular methods of verification used. These verification activities demonstrate that the possible risks identified are acceptable for the failure mode.

- A declaration of conformity with design controls

The Declaration of Conformity is provided in this Summary of Design Control.

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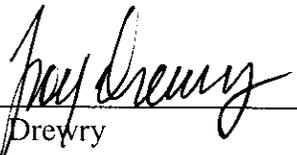
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Declaration of Conformity with Design Controls

Design Validation

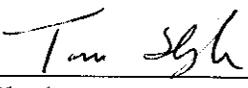
As required by risk analysis, all verification and validation activities for this submission were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. Additional testing above and beyond the required verification / validation activities included to establish equivalence to the predicate device may be performed in the future for internal purposes.



Troy Drewry Date 16 JAN 07
Group Director, Product Development

Manufacturing Facility

The Medtronic Sofamor Danek manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30, and the records are available for review.



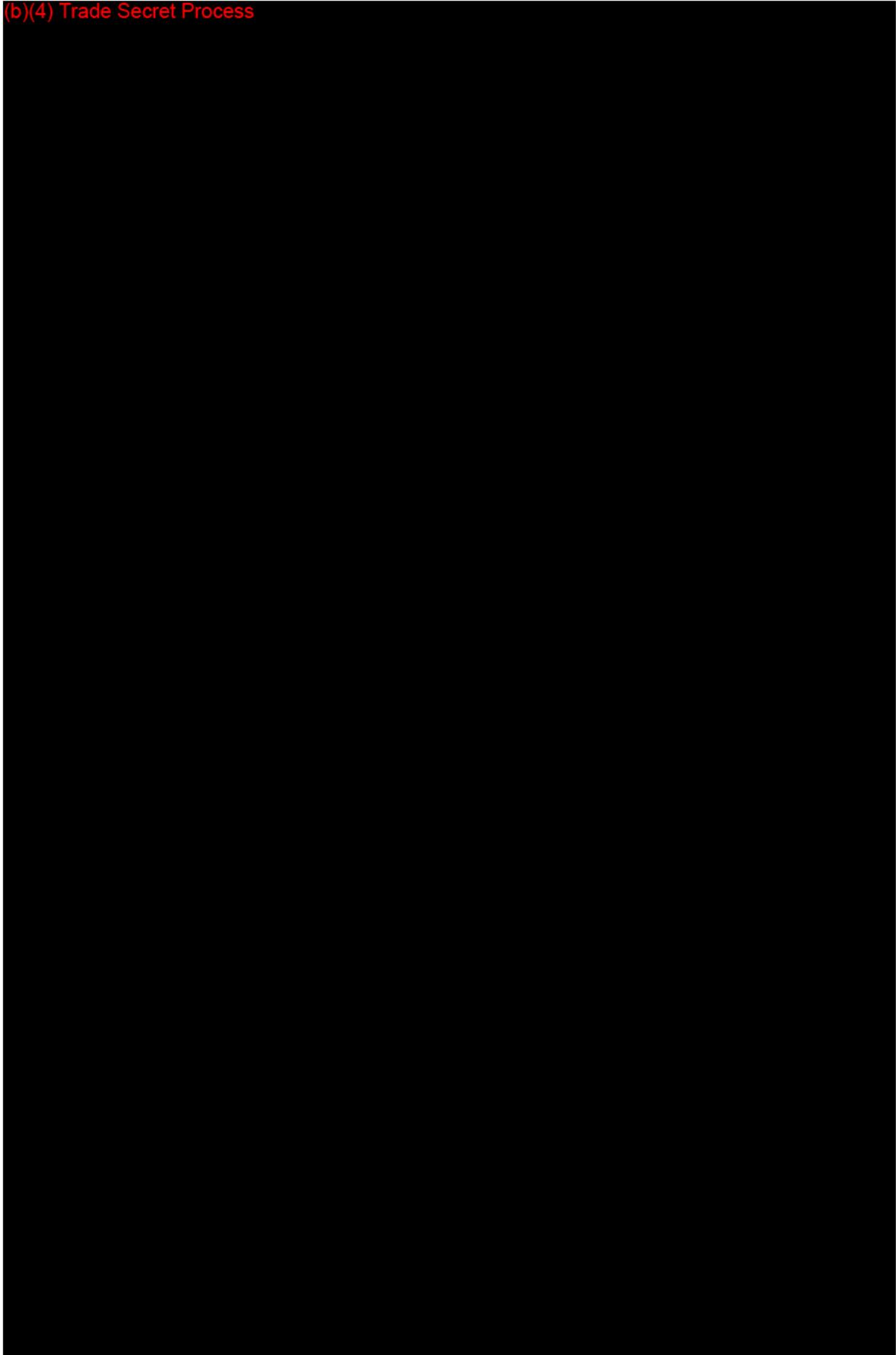
Tom Slagle Date 1/16/06
Senior Manager, Quality Engineering

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Risk Analysis for the VERTE-STACK[®] ANATOMIC PEEK[™] Spinal System

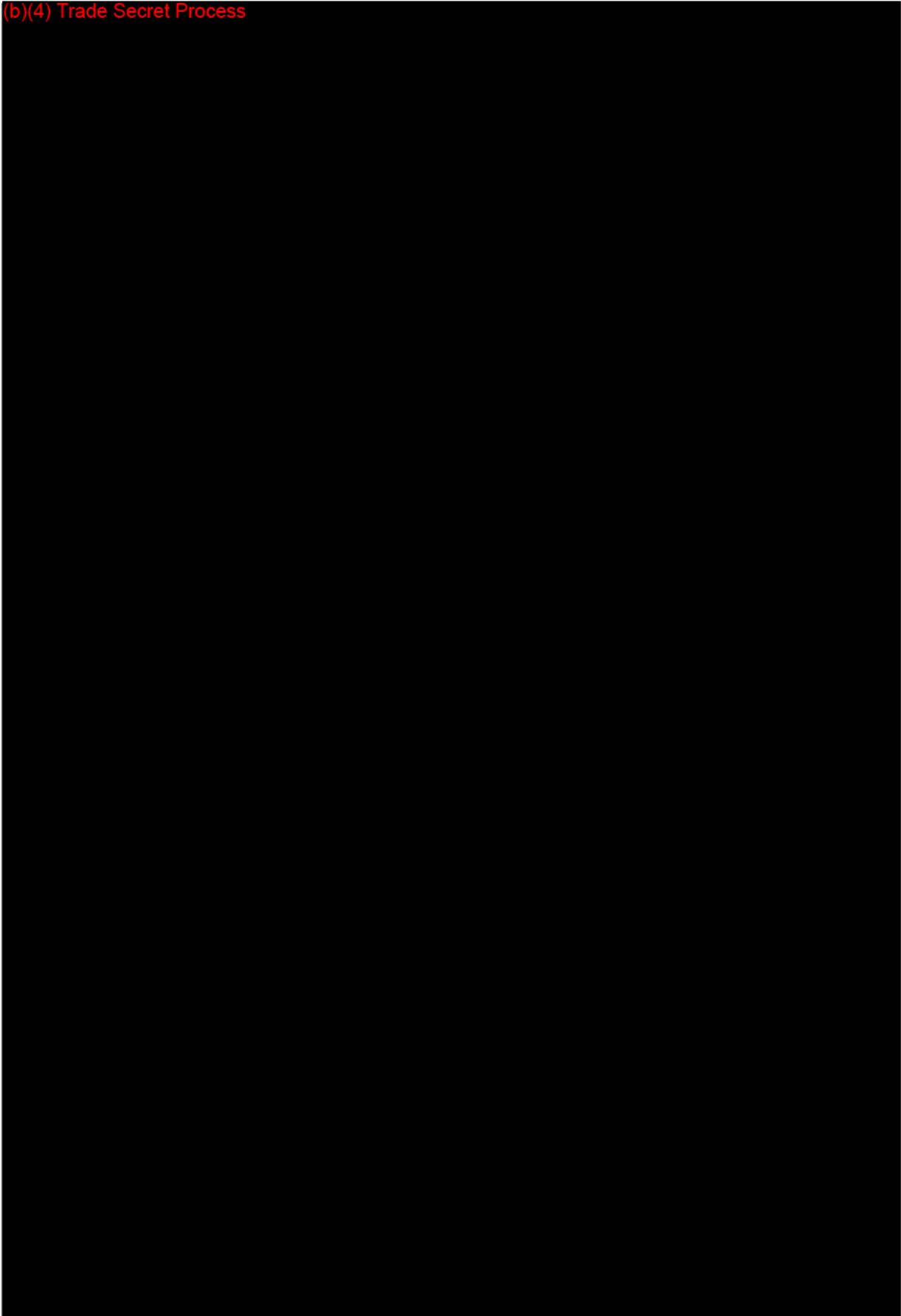
(b)(4) Trade Secret Process



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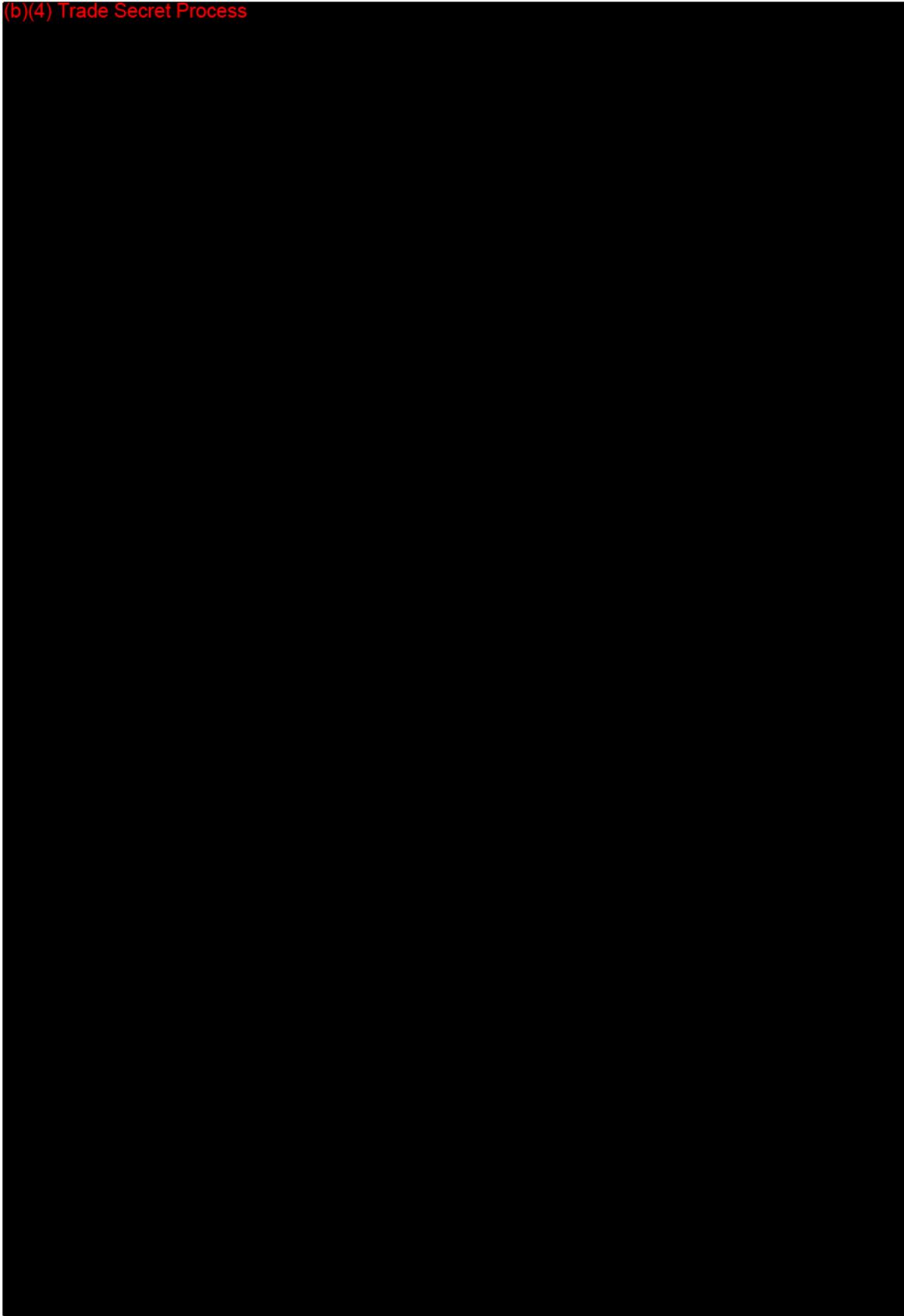
Risk Analysis for the VERTE-STACK® ANATOMIC PEEK™ Spinal System

(b)(4) Trade Secret Process



Risk Analysis for the VERTE-STACK® ANATOMIC PEEK™ Spinal System

(b)(4) Trade Secret Process



Risk Analysis for the VERTE-STACK® ANATOMIC PEEK™ Spinal System

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Written by:		Date: <u>1-9-07</u>
Product Development		
Approved by:		Date: <u>1-12-07</u>
Director Product Dev.		

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Attachment 2
Mechanical Testing

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Attachment 3

Sample Label

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Sample Label

 **Medtronic**


1800 PYRAMID PLACE
MEMPHIS, TN 38132, USA
(901) 396-3133
(800) 93-DANEK

REF: Y6240041
VERTE-STACK® Spinal System
ANATOMIC PEEK(TM)
Size: 10x14x11mm
Material: PEEK, Tantalum

LOT TEST



UCC: (01)00673978068633(17)100123(10)TEST
Sterility assured only when package is undamaged

 QTY: 1 EA
STERILE R


Use By
2010/01/23

Manufactured at: Degendorf GmbH

USA Rx only **CE** 0123

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Attachment 4

Draft Package Insert

000100

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VERTE-STACK® SPINAL SYSTEM



Medtronic B.V.
 Earl Bakkenstraat 10
 6422 PJ Heerlen
 The Netherlands
 Tel: + 31 45 566 80 00



Medtronic Sofamor Danek USA, Inc.
 1800 Pyramid Place
 Memphis, TN 38132
 Telephone 800 933 2635 (In U.S.A.)
 901 396 3133 (Outside of U.S.A.)
 Fax 901 396 0356

ENGLISH

IMPORTANT INFORMATION ON THE VERTE-STACK® SPINAL SYSTEM

The VERTE-STACK® Spinal System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. This system is indicated for single and two-level use only in the thoracic and lumbar anterior spine.

DESCRIPTION

The VERTE-STACK® device consists of hemi-cylindrical center cages of various lengths and diameters, as well as hemi-cylindrical add on cages of various lengths, diameters and angulation. The assembled VERTE-STACK® device consists of three components (one hollow center cage, and two hollow add-on cages). The VERTE-STACK® components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The design of the VERTE-STACK® device includes a variety of stackable components of different sizes and heights. The stackable components are designed to suit the individual patient pathology.

The VERTE-STACK® device may be used individually, or two or more may be stacked together in order to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The VERTE-STACK® Spinal System implant components are made of medical grade PEEK-OPTIMA LT1 along with a marker made from either Tantalum or titanium. Alternatively, VERTE-STACK® Spinal System may be manufactured from titanium alloy. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog for further information about warranties and limitations of liability.

The VERTE-STACK® Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK® constructs manufactured from PEEK may be used with stainless steel or titanium supplemental fixation devices. Titanium VERTE-STACK® constructs may not be used with stainless steel supplemental fixation devices. One of the following Medtronic spinal systems or their successors must be used with the VERTE-STACK® Spinal System.

	Anterior	Posterior
ZPLATE II™ Anterior Fixation System	√	
DYNA-LOK CLASSIC® Spinal System	√	√
VANTAGE® Anterior Fixation System	√	
TSRH® Spinal System	√	√
CD HORIZON® Spinal System	√	√

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Do not use implant components from any other manufacturer with VERTE-STACK® Spinal System components. Stainless steel and titanium implants are not compatible with each other. They must not be used together in a construct. As with all orthopedic implants, in no case may the implants be re-used.

INDICATIONS

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System and/or the GDLH® Spinal System. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

CONTRAINDICATIONS

The VERTE-STACK® device is not intended for cervical nor posterior surgical implantation.

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Suspected or documented metal allergy or intolerance.
9. Any case needing to mix metals from different components.
10. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
11. Any case not described in the indications.
12. Any patient unwilling to co-operate with postoperative instructions.
13. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. **Severe bone resorption.**
2. **Osteomalacia**
3. **Severe osteoporosis.**

POSSIBLE ADVERSE EVENTS

All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events or complications includes, but is not limited to:

1. Early or late loosening of the components. Implant migration.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
4. Infection.
5. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
6. Tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.

7. Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
8. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
9. Scar formation possibly causing neurological compromise around nerves and/or pain.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Bone loss or decrease in bone density, possibly caused by stress shielding.
12. Subsidence of the device into vertebral body(ies).
13. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
14. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
15. Non-union (or pseudarthrosis). Delayed union. Mal-union.
16. Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site-at, above, and/or below the level of surgery.
17. Graft donor site complications including pain, fracture, infection, or wound healing problems.
18. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
19. Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. This device system is not intended to be the sole means of spinal support. **The VERTE-STACK® device must be used with additional anterior or posterior instrumentation to augment stability.** Use of this product without a bone graft may not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good reduction are important considerations in the success of surgery. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Medtronic because the combination with other instrumentation may be incompatible, and may not be guaranteed.

The assembled parts have *in situ* length adjustment. The following information applies to the supplemental fixation device used in conjunction with the VERTE-STACK® device: Self-breaking plugs are provided for plate fixation to the cylinders. The final torque setting is determined by the rupture of the bolt. The screws should be tightened and broken off *in situ* after the final placement of the device. The broken part should not remain in the patient. **Never reuse an internal fixation device under any circumstances.** Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the

patient, the important medical information given in this document should be conveyed to the patient.

[USA] For US Audiences Only

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Plastic polymer implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. Further information on the use of this system will be made available on request.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the instrumentation, a bone graft should be used. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused. When using the VERTE-STACK® device, grafts containing autogenous bone should be used.
5. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is

- active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume excess alcohol during the bone graft healing process.
 3. The patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
 4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.
 5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Medtronic. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately resterilize all implants and instruments, which have been previously in the operation area. This process must be performed before handling or returning products to Medtronic.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened MEDTRONIC package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to MEDTRONIC. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

VERTE-STACK® Spinal System components may be provided sterile or non-sterile. Unless marked otherwise, implants from other Medtronic spinal systems specifically indicated for use with the VERTE-STACK® device, described in this insert are provided non-sterile and must be sterilized prior to use. Only sterile products should be placed in the operative field. Unless specified elsewhere these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes

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Steam*	Pre-Vacuum *	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic. Further, if any of the implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact MEDTRONIC.

Covered by one or more of U.S. Pat. Nos. 5,772,661; 5,860,973; 5,888,222; 6,746,484; 6,758,862; 6,830,570; and other pending patent applications.

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Attachment 5

510(k) Summary

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VERTE-STACK® Spinal System
510(k) Summary
January 2007

I. Company: Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

Contact: Christine Scifert, M.S., M.E.M.
Group Director, Regulatory Affairs

II. Proprietary Trade Name: VERTE-STACK® Spinal System

III. Classification Name/Product Code: Spinal Intervertebral Body Fixation Orthosis
(21 CFR 888.3060)

IV. Product Code: MQP

V. Product Description

The VERTE-STACK® device consists of hemi-cylindrical center cages of various lengths and diameters, as well as hemi-cylindrical add on cages of various lengths, diameters and angulation. The assembled VERTE-STACK® device consists of three components (one hollow center cage, and two hollow add-on cages). The VERTE-STACK® components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The design of the VERTE-STACK® device includes a variety of stackable components of different sizes and heights. The stackable components are designed to suit the individual patient pathology.

The VERTE-STACK® device may be used individually, or two or more may be stacked together in order to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The VERTE-STACK® Spinal System implant components are made of medical grade PEEK-OPTIMA LT1 along with a marker made from either Tantalum or titanium. Alternatively, VERTE-STACK® Spinal System may be manufactured from titanium alloy.

The VERTE-STACK® Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK® constructs manufactured from PEEK may be used with stainless steel or titanium supplemental

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fixation devices. Titanium VERTE-STACK® constructs may not be used with stainless steel supplemental fixation devices.

The purpose of this submission was to modify the geometry of the implants and to include additional sizes into the existing VERTE-STACK® Spinal System.

V. Indications

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System and/or the GDLH® Spinal System. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

VI. Substantial Equivalence

Documentation, including mechanical test results, was provided which demonstrated that the subject VERTE-STACK® Spinal System components are substantially equivalent to the previously cleared VERTE-STACK® Spinal System (K052931, SE 11/13/2005; and K062133, SE 09/26/2006).

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Attachment 6

Implant/Instrument List

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Attachment 7
Engineering Drawings

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Attachment 8

Indications of Use Statement

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000163

January 2007

510(k) Number (if known): _____

Device Name: VERTE-STACK® Spinal System

Indications for Use:

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK CLASSIC® Spinal System, the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System and/or the GDLH® Spinal System. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

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)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Deepa Gavini

Subject: 510(k) Number K070173/S

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices. *Deepa Gavini 3/12/07*
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

87 MQP, Class II, 21 CFR 888.3060

Review: [Signature] OSDB 3/13/07
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 3/13/07
(Division Director) (Date)

510(K) MEMORANDUM

DATE: March 12, 2007

RE: Special 510(k): Device Modification
K070173/S1
Trade Name: VERTE-STACK® Spinal System
Device Identification: 87 MQP, Class II, 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis

SPONSOR: Medtronic Sofamor Danek
Contact: Christine Scifert
Group Director, Regulatory Affairs
Phone: 901-344-1538
Fax: 901-346-9738
Email: christine.scifert@medtronic.com

May Todd Cottle 5/12/07
Deepa Gavini 3/12/07

REVIEWER: Deepa Gavini, Biomedical Engineer
DGRND/Orthopedic Spine Devices Branch, HFZ-410

RECOMMENDATION: I recommend this application be found substantially equivalent (SE).

Purpose

This submission contains responses to the February 22, 2007 additional information letter. This

(b)(4) Trade Secret Process - Product Specs

Internal Administrative Form

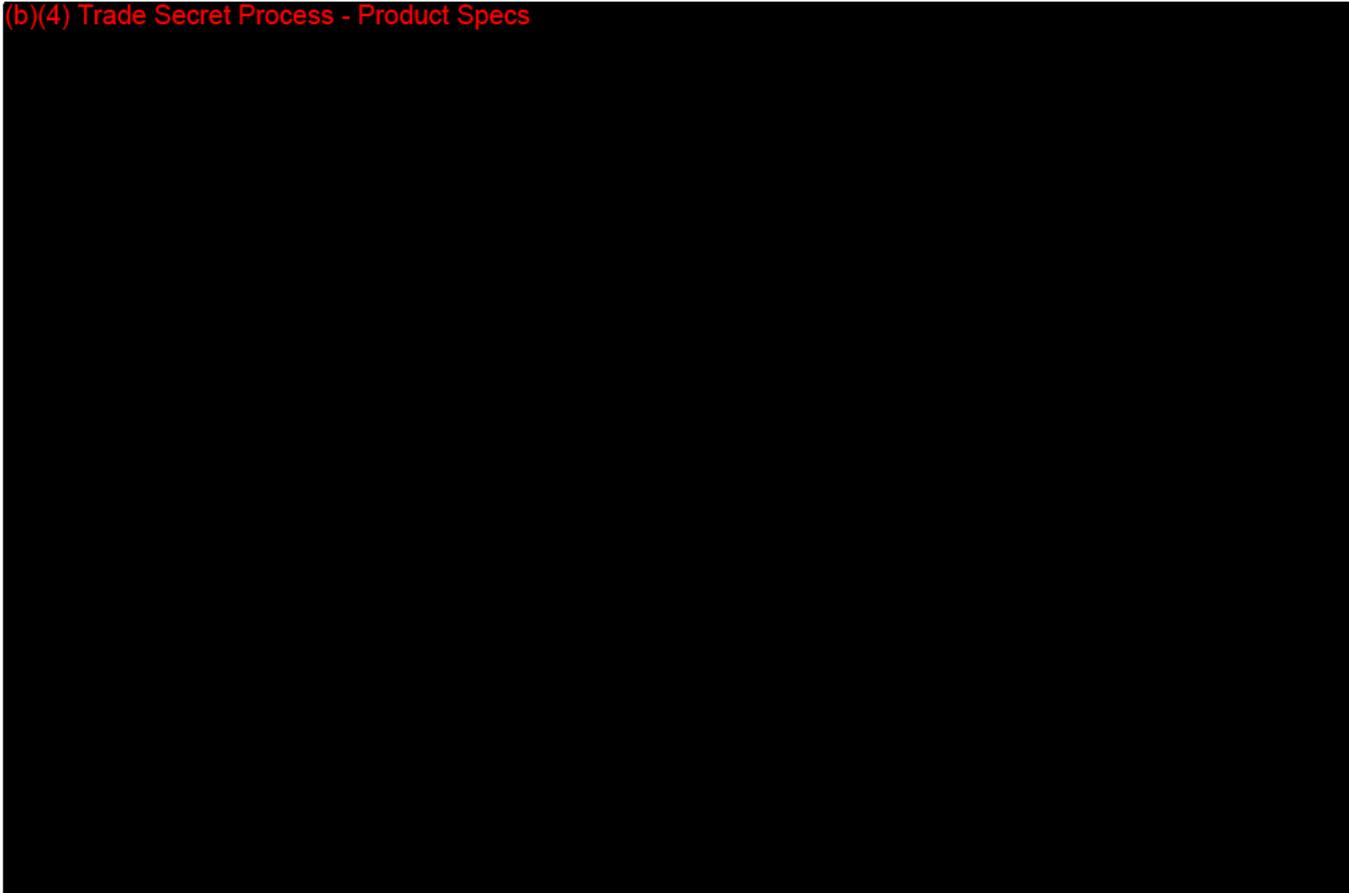
	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		N/A
3. Have you verified that the Document is labeled Class III for GMP purposes?		N/A
4. If not, has POS been notified?		N/A
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		N/A
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If yes, consult the ODE Integrity Officer.		N/A
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.)		N/A

Decision Making Rationale

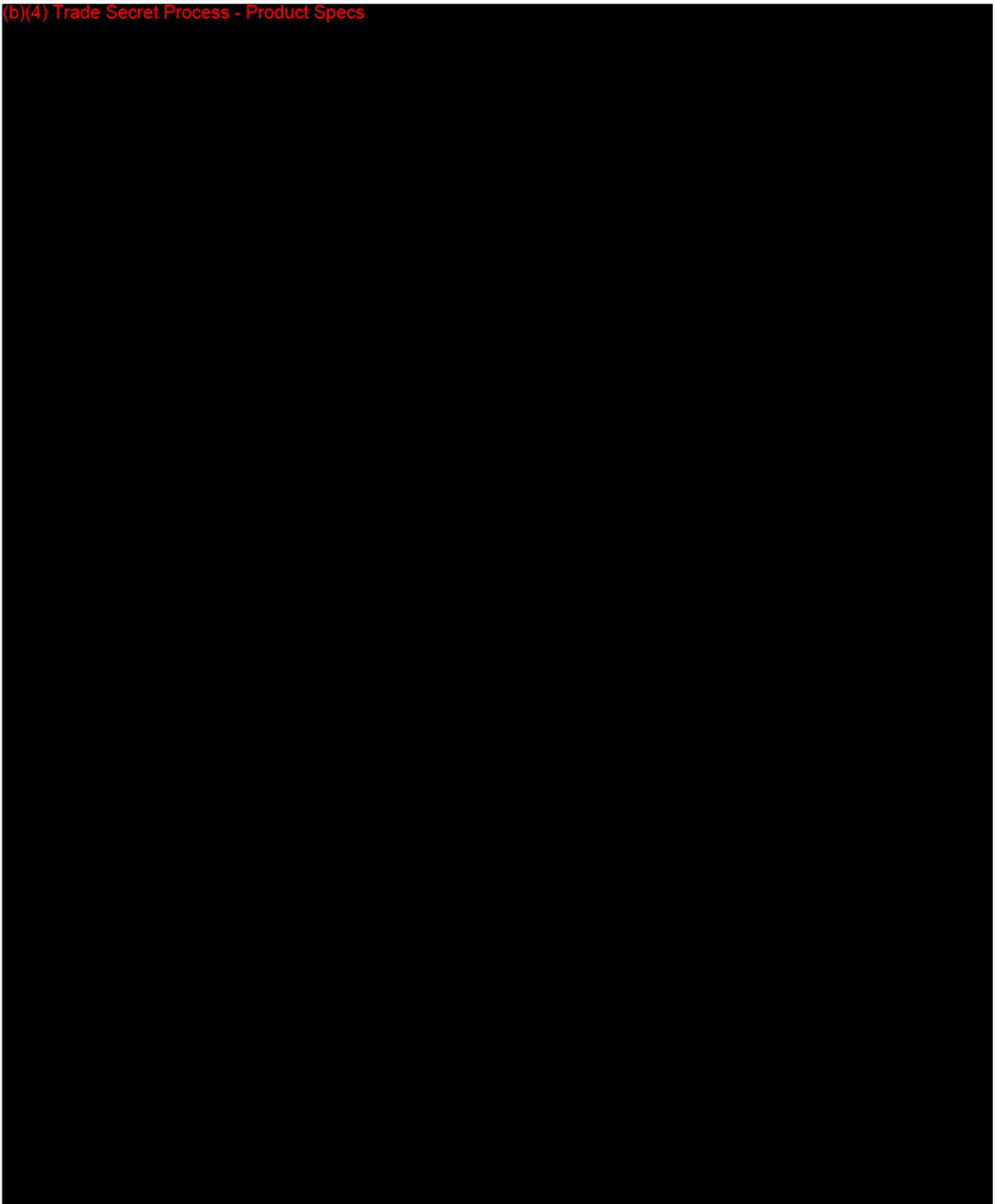
		YES	NO	
1.	Is Product A Device	X		If NO = Stop
2.	Is Device Subject To 510(k)?	X		If NO = Stop
3.	Same Indication Statement?	X		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5.	Same Technological Characteristics?	X		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?	X		If NO = Request Data
11.	Data Demonstrate Equivalence?	X		Final Decision: SE

Supplement 1

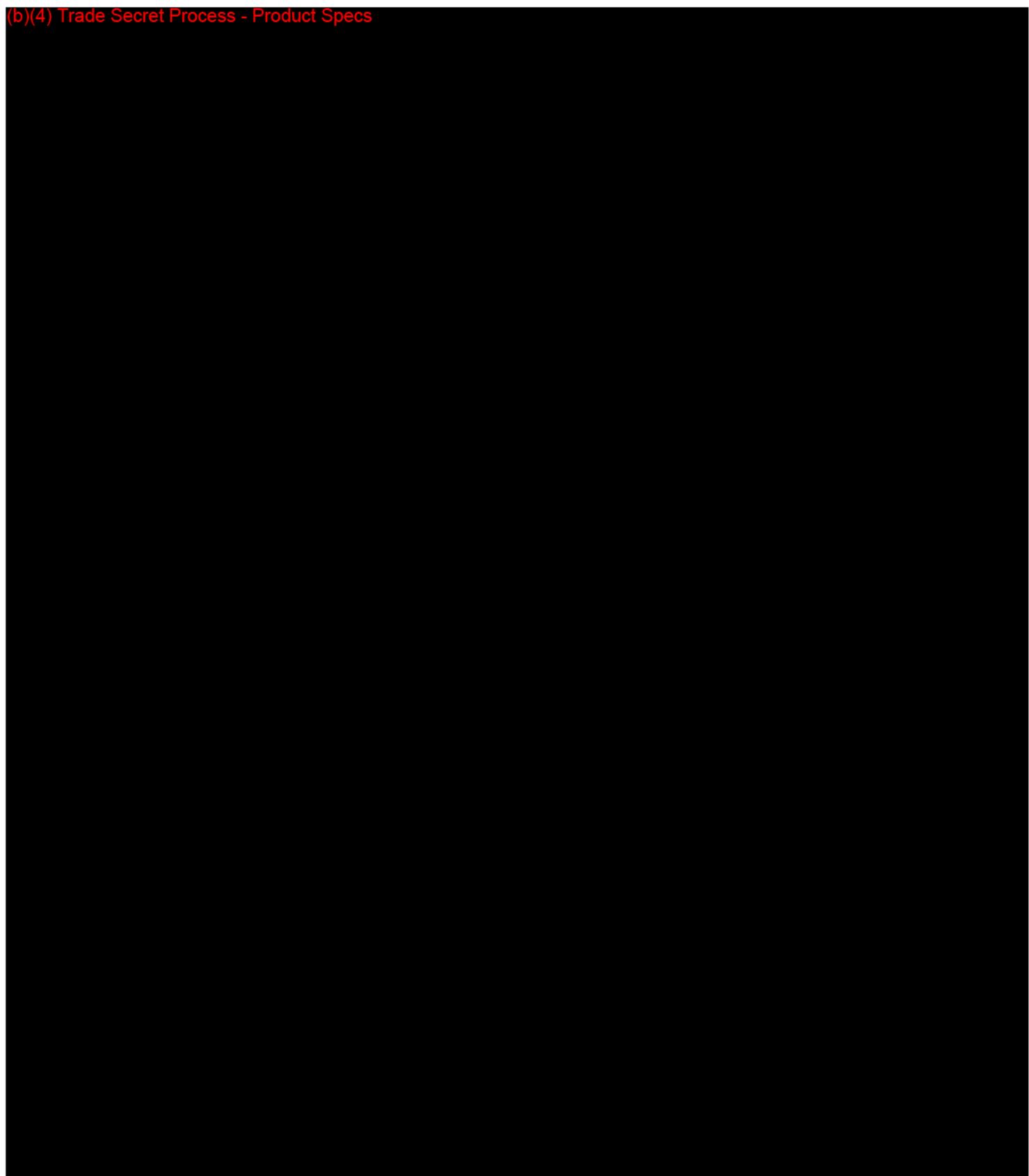
(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



Conclusion

The sponsor has provided adequate responses to all deficiencies. With all other administrative requirements fulfilled, I recommend the VERTE-STACK® Spinal System be found substantially equivalent (SE) to legally marketed devices. A K1(A)-SE letter should be sent to the sponsor.

From: Reviewer(s) - Name(s) Deepa Gavini

Subject: 510(k) Number K070173

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept). *Deepa Gavini 2/19/07*
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- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

- Truthful and Accurate Statement Requested Enclosed
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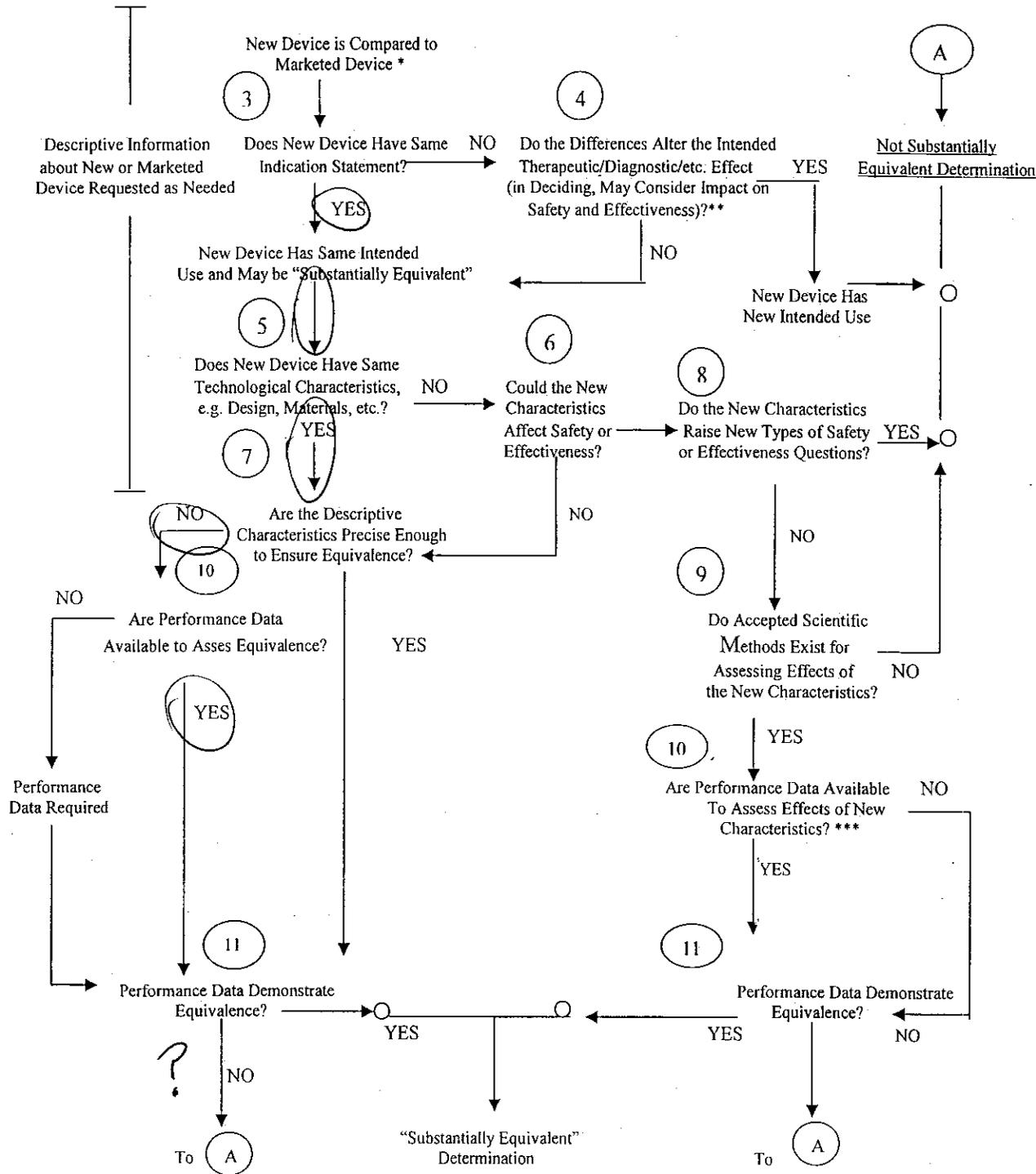
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

87 MQP, Class II, 21 CFR 888.3060

Review: [Signature] OS03 2/19/07
(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.

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K070173

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510]] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510]] Manual.		✓
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.		✓
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	N/A	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510]] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

642

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		✓
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: Dupa Duvic

Concurrence by Review Branch: _____

Date: _____

510(K) MEMORANDUM

*also reviewed by:
Srij de M CSM 2/9/07*

DATE: February 5, 2007

RE: Special 510k: Device Modification
 K070173: VERTE-STACK® Spinal System
 Device Identification: 87 MQP, Class II, 21 CFR 888.3060
 Regulation Name: Spinal intervertebral body fixation orthosis

SPONSOR: Medtronic Sofamor Danek
 Contact: Christine Scifert
 Group Director, Regulatory Affairs
 Phone: 901-344-1538
 Fax: 901-346-9738
 Email: christine.scifert@medtronic.com

REVIEWER: Deepa Gavini, Biomedical Engineer *Deepa Gavini 2/9/07*
 DGRND/Orthopedic Spine Devices Branch, HFZ-410

RECOMMENDATION: I recommend this application be placed on hold for **additional information.**

Purpose

This submission seeks approval for new VERTE-STACK® ANATOMIC PEEK™ components, to be used in vertebral body replacements. Modifications were made upon the locking mechanism, convexity of the superior surface, lateral ports and footprints of the construct.

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		X
2. Did we grant expedited review?		X
3. Have you verified that the Document is labeled Class III for GMP purposes?		N/A
4. If not, has POS been notified?		N/A
5. Is the product a device?	X	
6. Is the device exempt from 510(k) by regulation or policy?		X
7. Is the device subject to review by CDRH?	X	
8. Are you aware that this device has been the subject of a previous NSE decision?		X
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		N/A
10. Are you aware of the submitter being the subject of an integrity investigation?		X
11. If yes, consult the ODE Integrity Officer.		N/A
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.)		N/A

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Subject 510k

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

K062133 – VERTE-STACK Spinal System
K061938 – VERTE-STACK Spinal System (b)(4)
K052931 – VERTE-STACK Spinal System (b)(4)
K043561 – VERTE-STACK Spinal System (b)(4) Trade
K041197 – VERTE-STACK Spinal System (b)(4)
K041556 – VERTE-STACK Spinal System (b)(4)
K031780 – VERTE-STACK Spinal System (b)(4) Trade
K030736 – VERTE-STACK Spinal System (b)(4) Trade Secret Process) Secre
K030601 – VERTE-STACK Spinal System (b)(4) Trade Secret
K023570 – VERTE-STACK Spinal System (b)(4) Trade Secret Process - Product
K023887 – VERTE-STACK Spinal System (b)(4) Trade Secret Process - Product
K021791 – VERTE-STACK Spinal System (b)(4) Trade

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.

"The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic ZPLATE II™ Anterior Fixation System, the DYNA-LOK® CLASSIC Spinal System, the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System and/or the GDLH® Spinal System. Additionally, the VERTE-STACK® device is intended to be used with bone graft."

Comments: The intended/indications for use are identical to those cleared through K052931 and K062133.

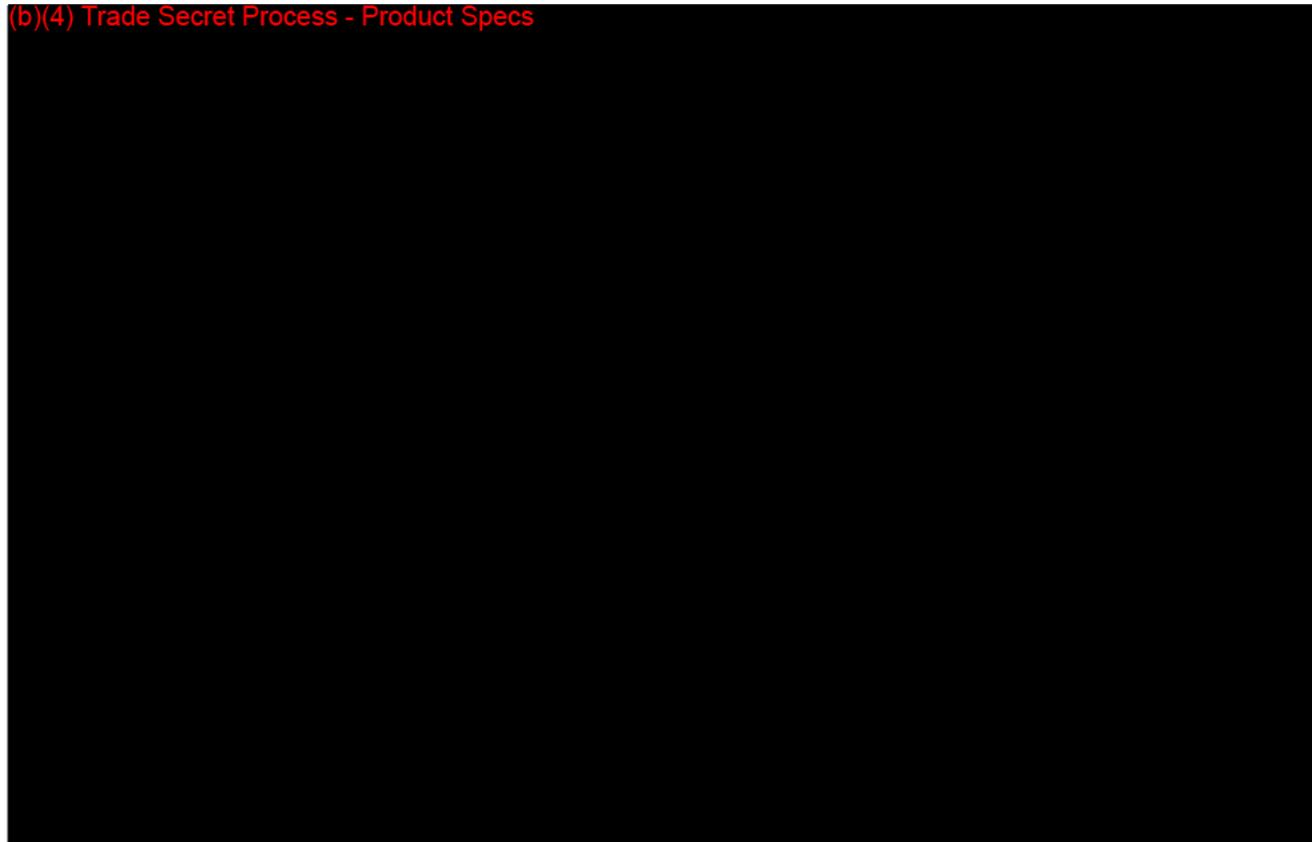
3. A description of the device **MODIFICATIONS**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

The new set of VERTE-STACK® ANATOMIC PEEK™ constructs are intended to contribute to the structural stability of the spine after a corpectomy, when used in conjunction with

supplemental fixation devices. The constructs consist of a central centerpiece (strut) and two smaller end pieces (end caps), which will be placed between two vertebrae through an anterior surgical approach. The VERTE-STACK® construct can be used in place of a single vertebra, or they can be stacked to replace two adjacent vertebrae.

The VERTE-STACK® components are constructed from PEEK Optima LT1 and contain Tantalum markers. These constructs will be gamma sterilized using the same process as predicate devices (K052931 and K062133).

(b)(4) Trade Secret Process - Product Specs



Due to the large number of new components, please refer to Attachment 6 for a complete table of system components.

Refer to Attachment 7 for engineering drawings of all new components.

(b)(4) Trade Secret Process - Product Specs



4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and

(see #3 above)

5. A **Design Control Activities Summary** which includes:

- a) *Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.*

Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

Risk assessment was provided in Attachment 1 of the submission, summarized on the following page.

Risks/Verification Activities

To address the risk of mechanical failure due to the modifications, the sponsor utilized the subsequent tests as verification activities: static compression, dynamic compression, static torsion, dynamic torsion, subsidence and expulsion. These tests are sufficient in the analysis of this device, as stated in the "Guidance for Industry and FDA Staff: Spinal System 510(k)s".

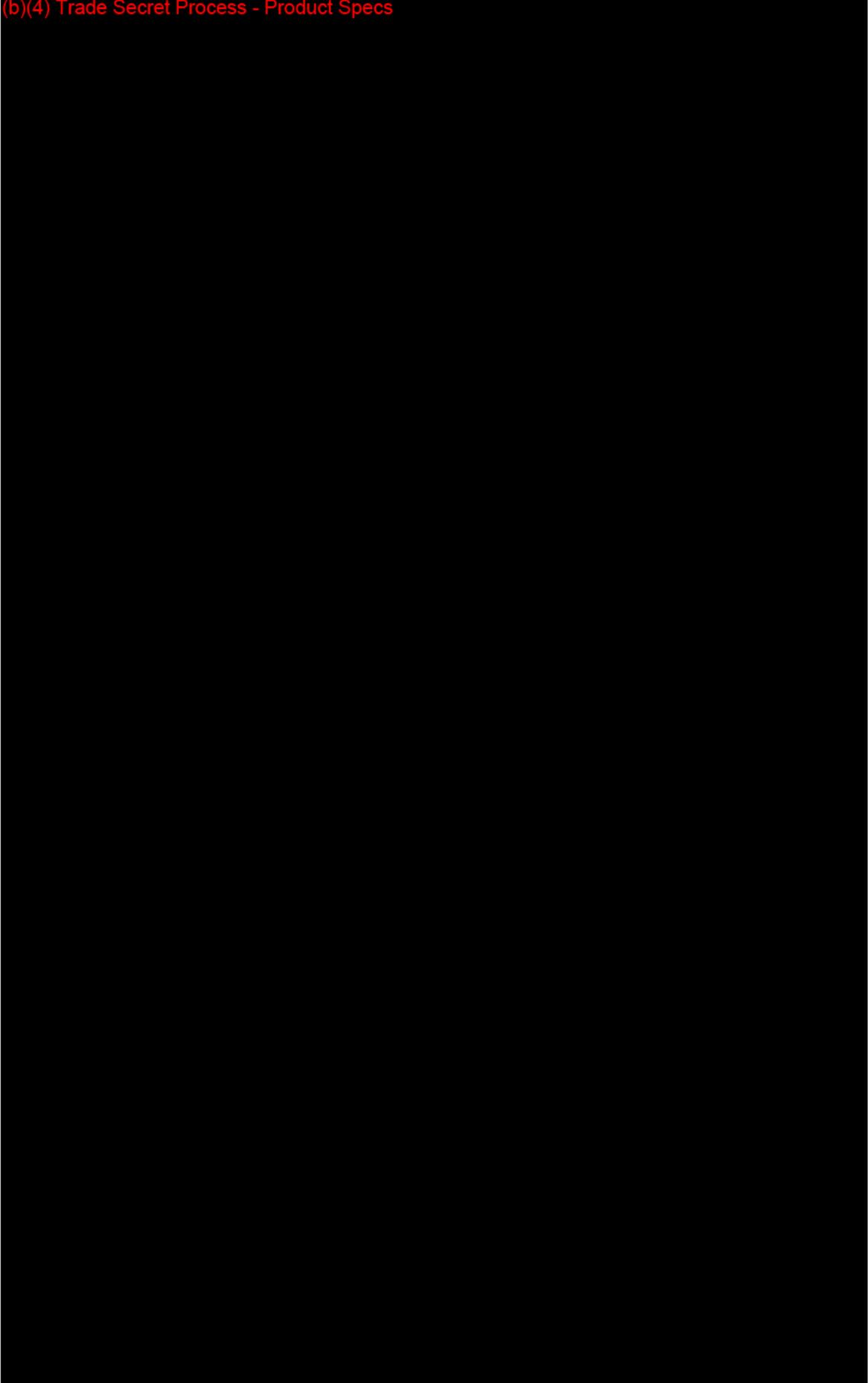
(b)(4) Trade Secret Process - Product Specs



Acceptance Criteria

The acceptance criteria are stated within the "Acceptance Criteria" column of the Risk Analysis Summary table.

(b)(4) Trade Secret Process - Product Specs



(b)(4) Trade Secret Process - Product Specs



- b) *A declaration of conformity with design controls. The declaration of conformity should include:*
- i) *A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and*
 - ii) *A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.*

A Declaration of Conformity is provided in Amendment 1 of the submission.

(b)(4) Trade Secret Process - Product Specs



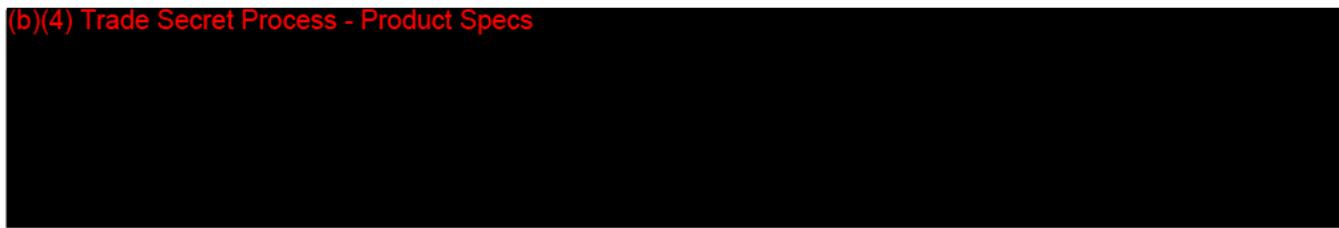
6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and an Indications for Use Enclosure.

A Truthful and Accurate Statement (page 9), a 510(k) Summary (Attachment 5), and an Indications for Use Statement (Attachment 8) are included in the submission.

7. The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification.

A sample label (Attachment 3) and a package insert (Attachment 4) are provided in the submission.

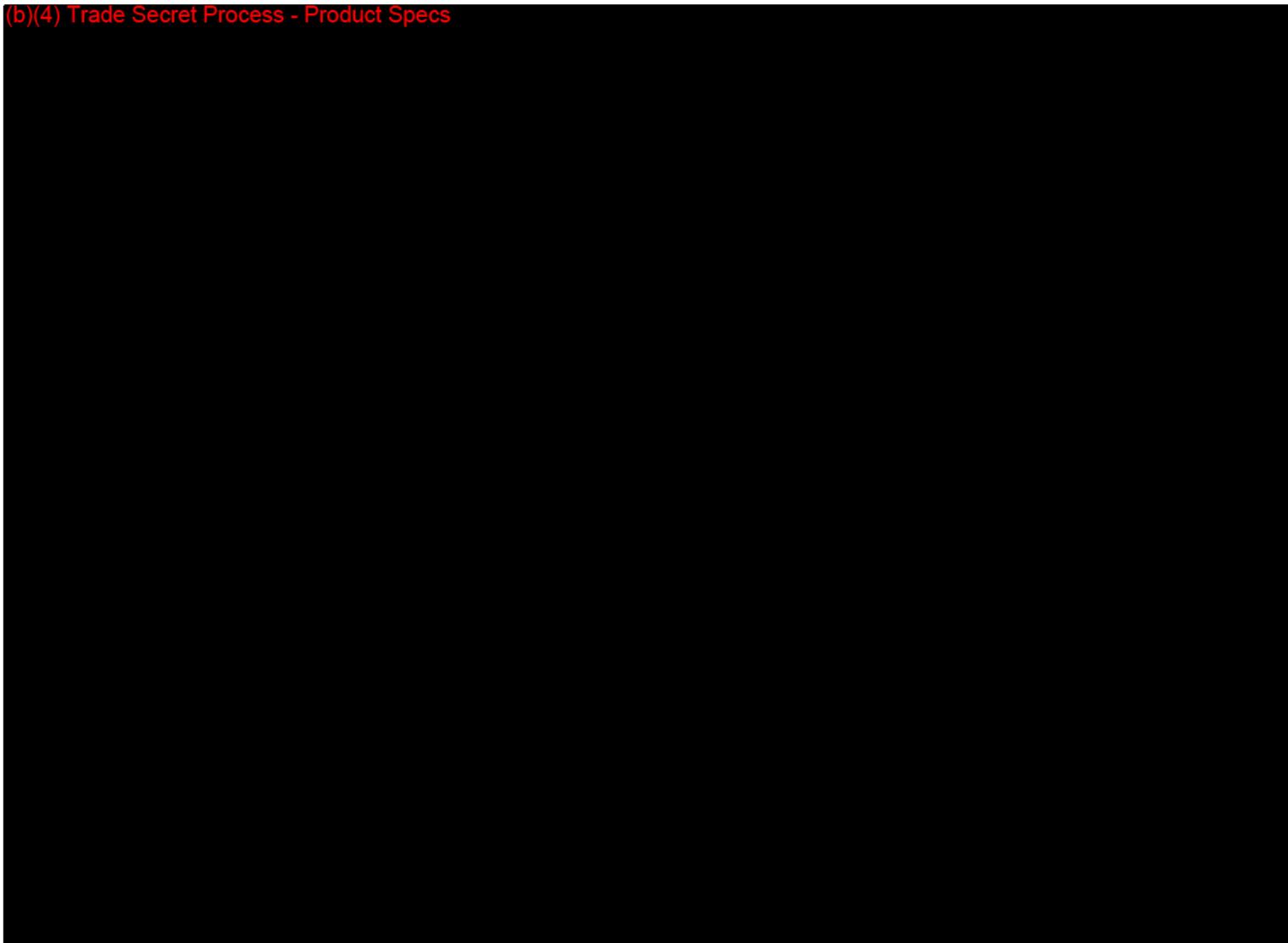
(b)(4) Trade Secret Process - Product Specs



8. *In addition, the submitter's description of the particular modifications and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed.*

A determination of substantial equivalence cannot be made at this time with the information provided. I recommend this 510(k) be placed on hold for **additional information**.

(b)(4) Trade Secret Process - Product Specs

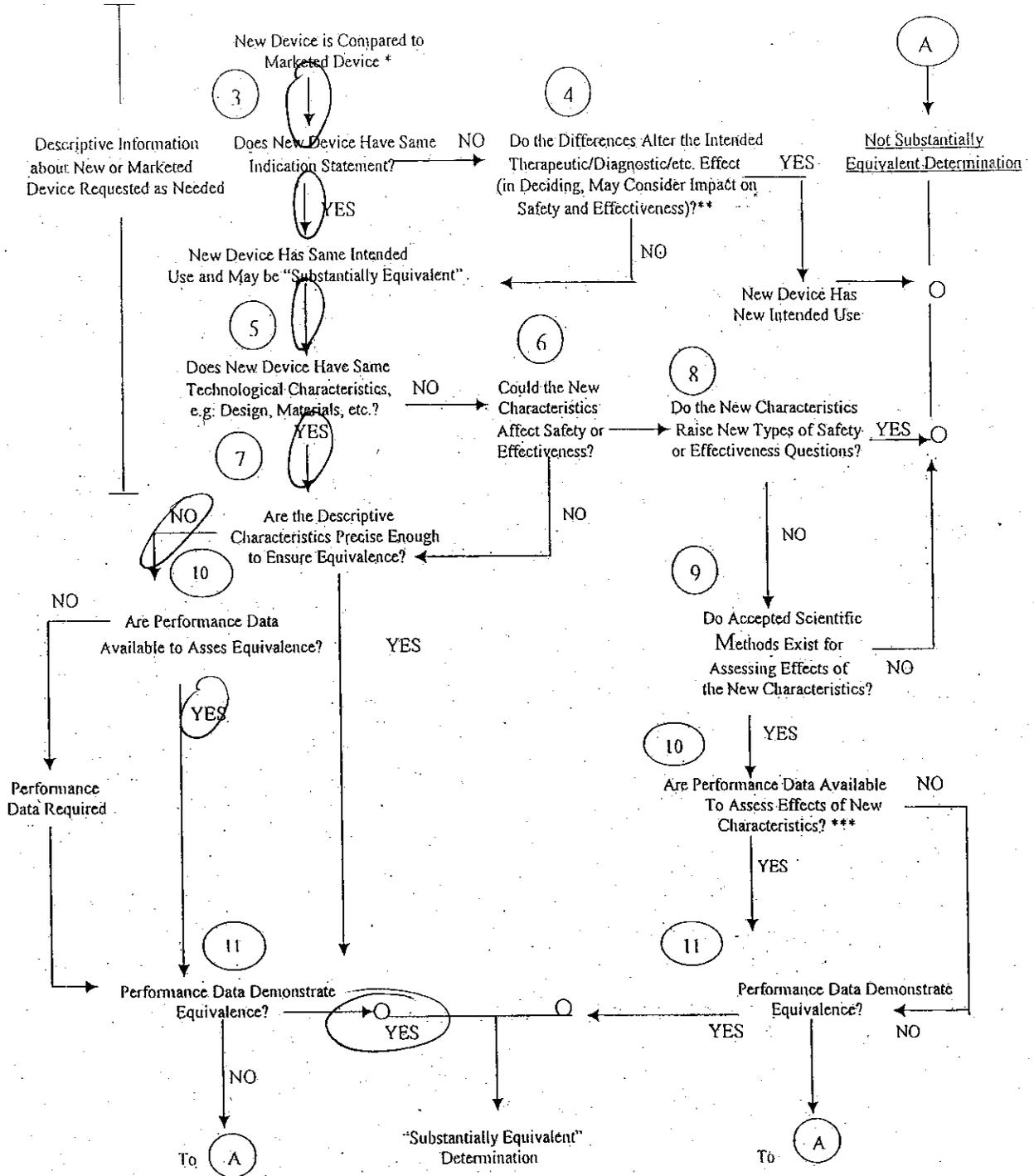


10. Decision Making Rationale

		YES	NO	
1.	Is Product A Device	X		If NO = Stop
2.	Is Device Subject To 510(k)?	X		If NO = Stop
3.	Same Indication Statement?	X		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5.	Same Technological Characteristics?	X		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?	X		If NO = Request Data
11.	Data Demonstrate Equivalence?		X	Final Decision: AI

END OF REVIEW

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.

February 26, 2007

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40)
9200 Corporate Blvd.
Rockville, Maryland 20850

MEDTRONIC SOFAMOR DANEK, INC.
1800 PYRAMID PL.
MEMPHIS, TN 38132
ATTN: CHRISTINE SCIFERT

510(k) Number: K070173
Product: VERTE-STACK
SPINAL SYSTEM

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 (HFZ-401) 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 www.fda.gov/cdrh/ode/a02-01.html. 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/cdrh/ode/guidance/1567.html>. 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.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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



Medtronic

K070173/S'

Medtronic Inc.
500 Franklin Road, Denville, NJ 07834
800.876.0113
www.medtronic.com

RECEIVED

FEB 25 10 33

K-25

February 22, 2007

Document Control Clerk
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mailing Center (HFZ-401)
9200 Corporate Blvd., Room 20N
Rockville, Maryland 20850

Re: Special 510(k): VERTE-STACK® Spinal System
Medical Specialty: General and Restorative and Neurological Device
Legally Marketed Device: VERTE-STACK® Spinal System

ATTN: Mr. Sergio de del Castillo

RE: VERTE-STACK® Spinal System – K070173

Dear Document Control Clerk:

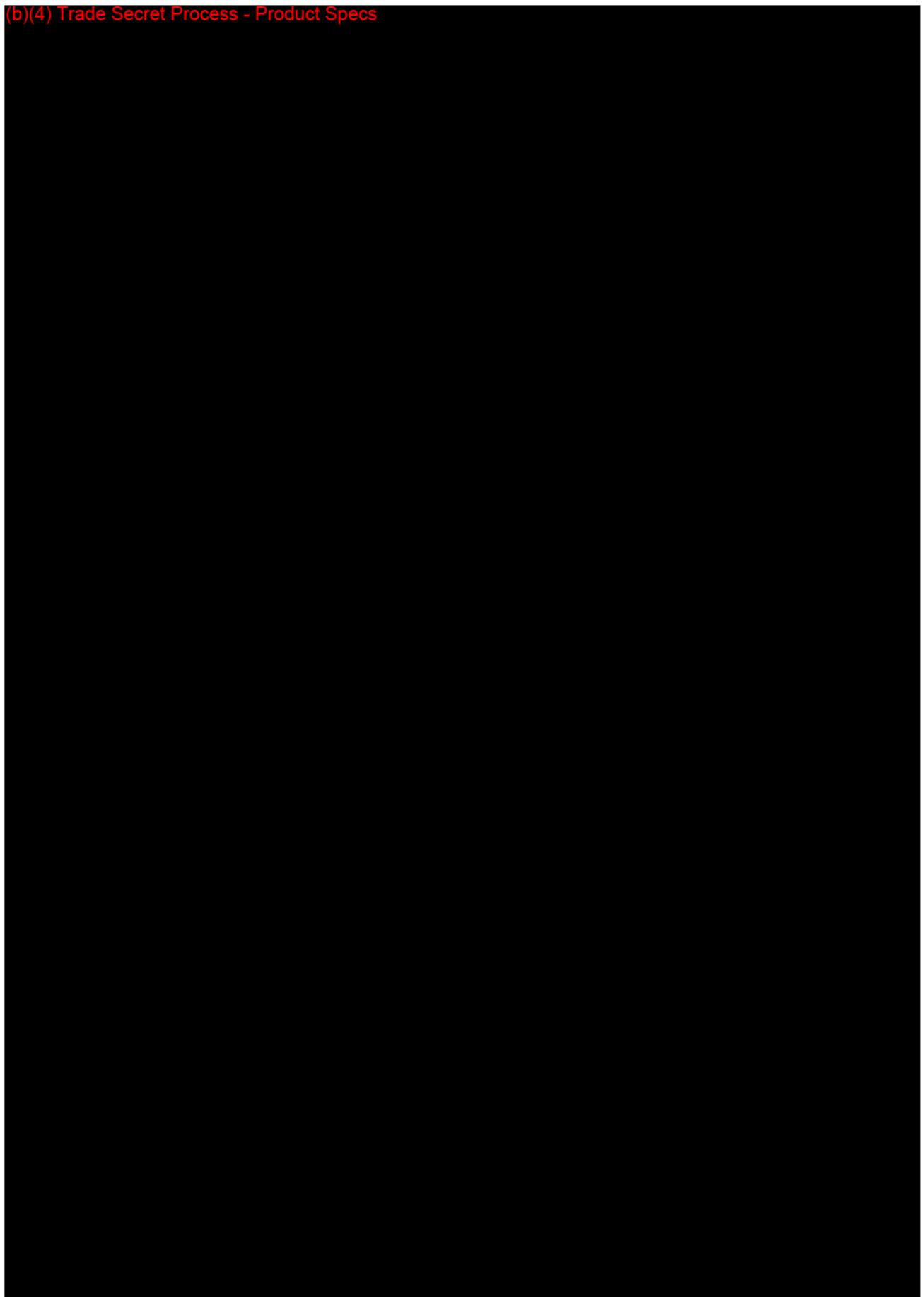
On February 16, 2007, we received a letter from the FDA reviewer to provide additional information regarding the VERTE-STACK® Spinal System Special 510(k) submission (K070173) currently being reviewed by the agency. (b)(4) Trade Secret Process - Product

Specs

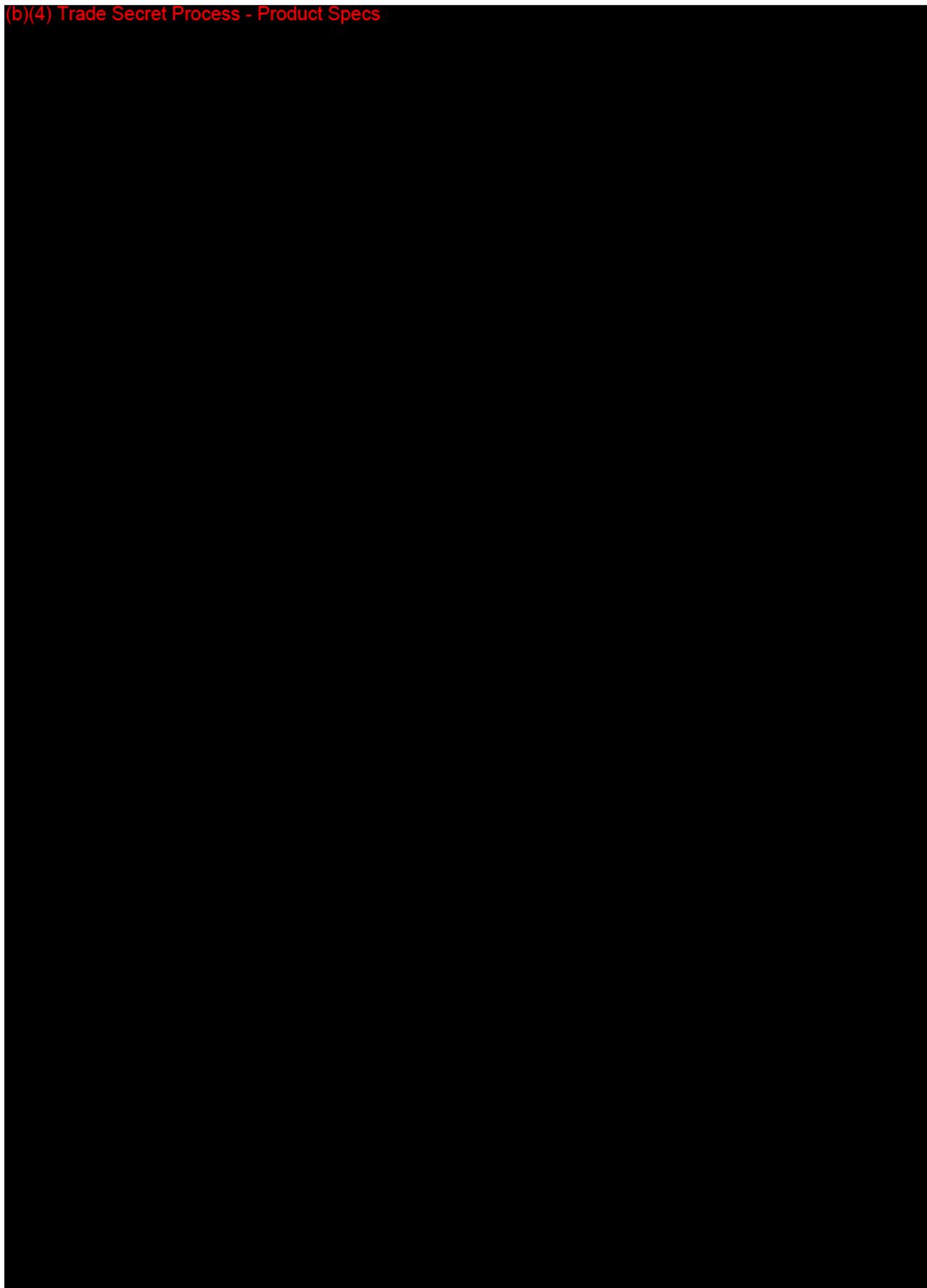
(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

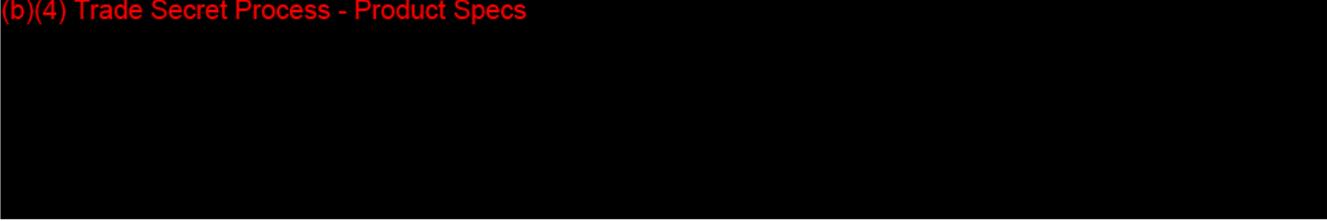


(b)(4) Trade Secret Process - Product Specs

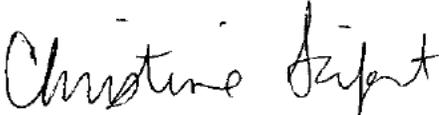


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(b)(4) Trade Secret Process - Product Specs



Sincerely,



Christine Scifert, M.S., M.E.M.,
Group Director, Regulatory Affairs
Attachments

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Attachment 10
Engineering Drawings

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Attachment 11

Summary of Design Controls/Risk Analysis

Summary of Design Control Activities for the modified components of the VERTE-STACK® Spinal System

In this summary, we provide appropriate supporting data of design control activities within the meaning of §807.87(g). This summary includes the following:

- An identification of the Risk Analysis methods used to assess the impact of the modification on the device and its components as well as the results of the analysis:

A Failure Mode and Effects Analysis was performed to identify possible hazards associated with the modified features of the VERTE-STACK® Spinal System. A summary of this analysis is included in this Summary of Design Control Activities.

- An identification, based on the Risk Analysis, of the verification and/or validation activities performed, including methods or tests used and the acceptance criteria applied

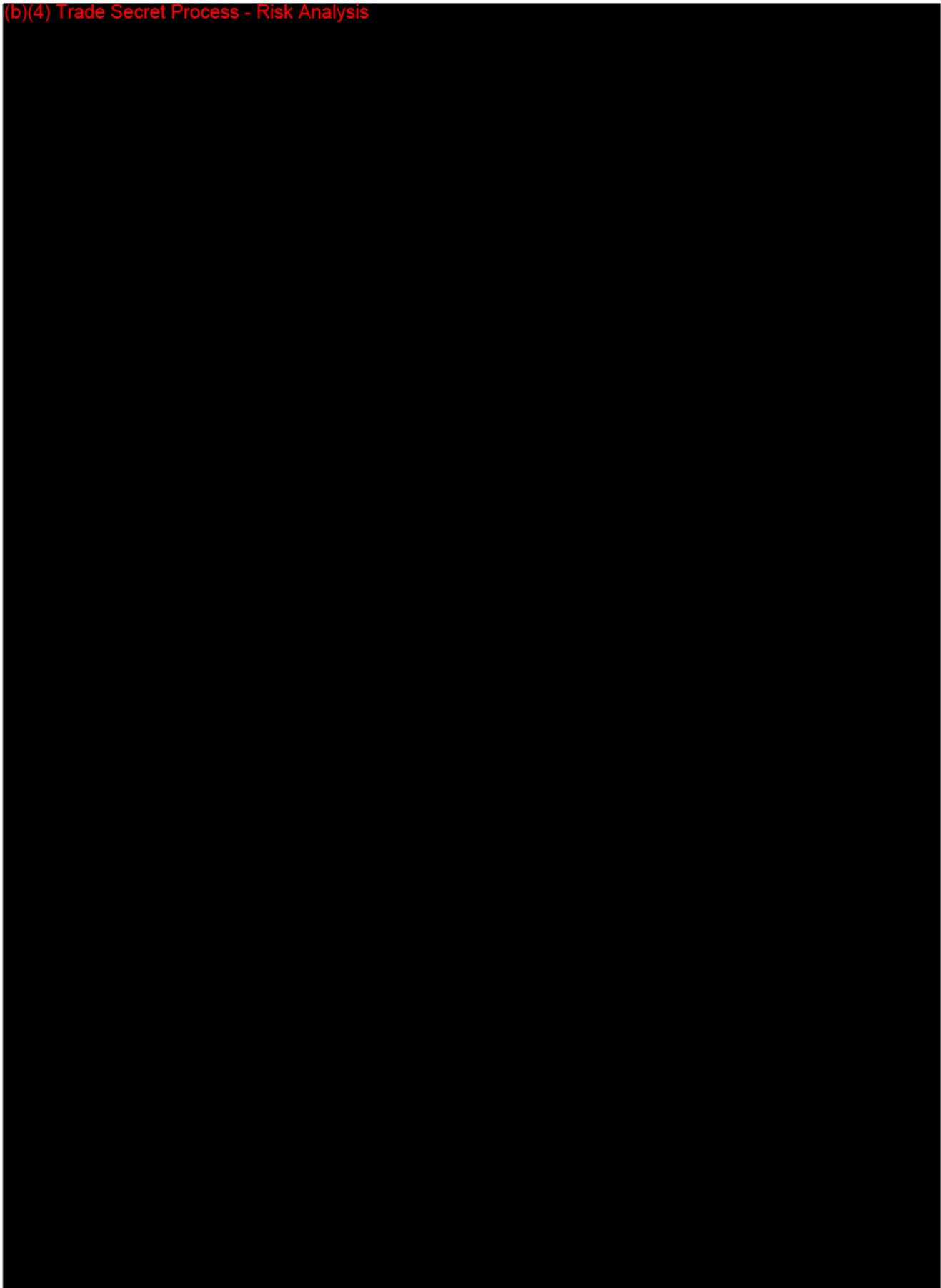
Based on the possible hazards identified in the Failure Mode and Effects Analysis, design verification was performed. A summary of this Design Verification is included in this Summary of Design Control and identifies the particular methods of verification used. These verification activities demonstrate that the possible risks identified are acceptable for the failure mode.

- A declaration of conformity with design controls

The Declaration of Conformity is provided in this Summary of Design Control.

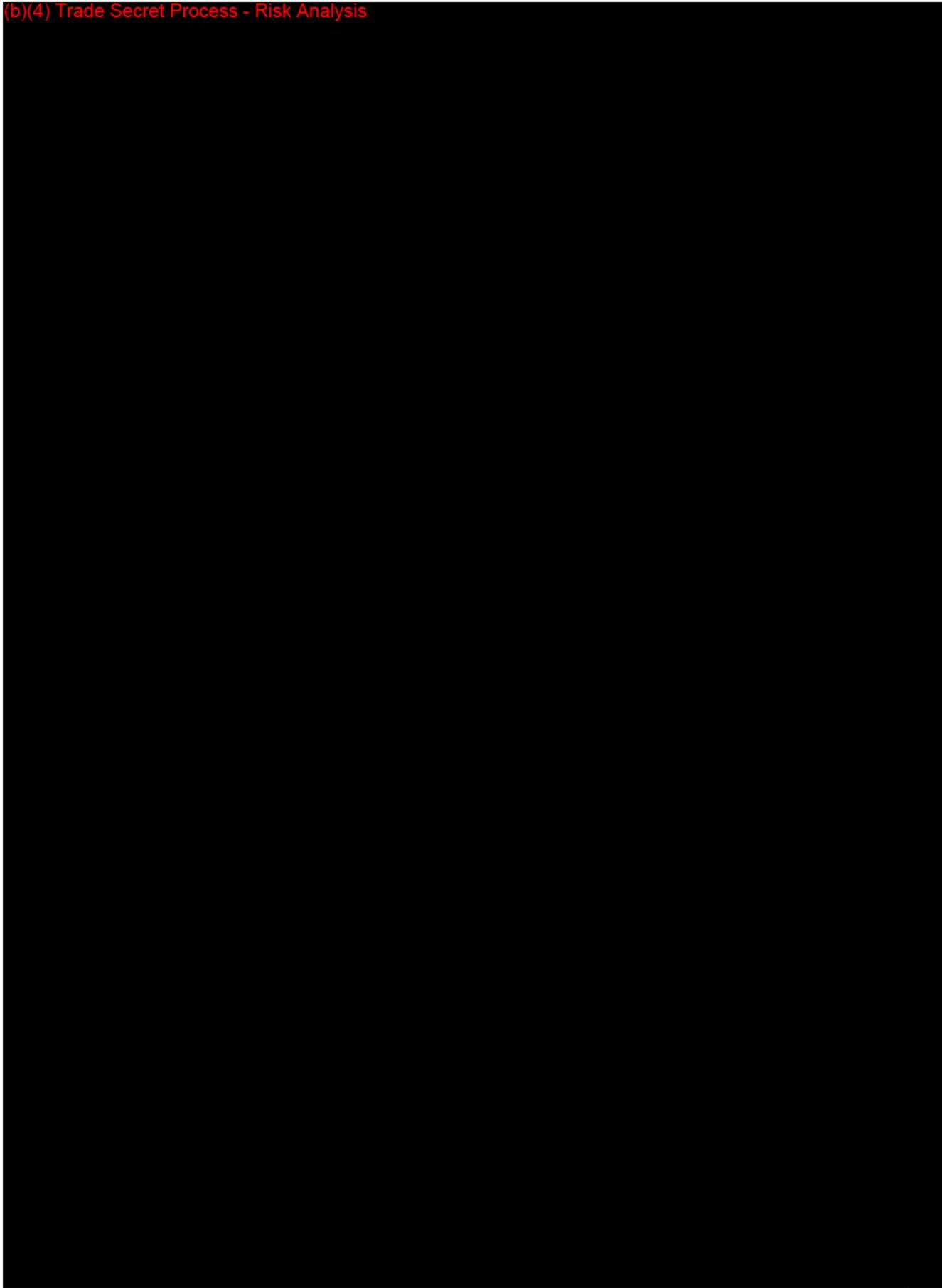
Risk Analysis for the VERTE-STACK® ANATOMIC PEEK™ Spinal System

(b)(4) Trade Secret Process - Risk Analysis



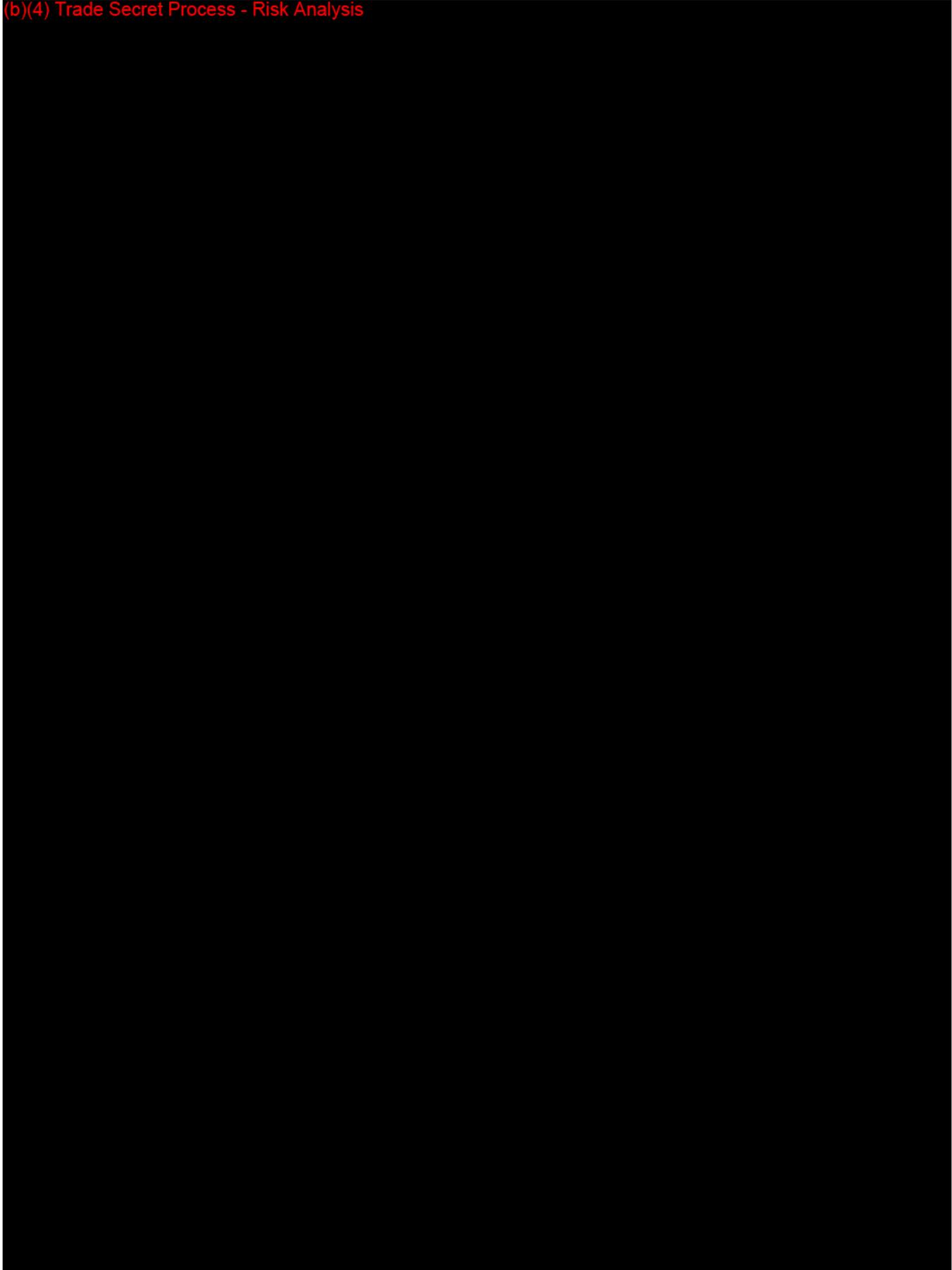
Risk Analysis for the VERTE-STACK® ANATOMIC PEEK™ Spinal System

(b)(4) Trade Secret Process - Risk Analysis



Risk Analysis for the VERTE-STACK® ANATOMIC PEEK™ Spinal System

(b)(4) Trade Secret Process - Risk Analysis



Risk Analysis for the VERTE-STACK® ANATOMIC PEEK™ Spinal System

Written by: [Signature] Date: 2-20-07
Product Development

Approved by: [Signature] Date: 2-20-07
Director Product Dev.

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*The foam test blocks mean stiffness of 301 N/mm ± 56 N/mm is statistically equal to the mean stiffness of the predicate device's foam test blocks

CDs Received

3

WITS Entry

1 CD with entire submission

1CDT

CDs with entire submission

XCDT

1 CD with each copy of submission

1CDPC

CDs with each copy of submission

XCDPC

Check here if CDs were bound into volume(s)

XCDTB - XCDPCB

Letter Stated CD(s) - NO CDs found in Packaging

LSCD - NO CDs

True Electronic Submission (E-Copy) -- w/proper cover letter stating so ESUB 1/X - 1 or X

This disc contains Medtronic proprietary information. Unauthorized viewing and copying are strictly prohibited.

VERTE-STACK ANATOMIC PEEK
K070173 Additional Information Special 510(K)



Medtronic

February 23, 2007

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