USER:	**(ldt)**
FOLDER:	**K052931 - 149 pages (FOI:06007632)**
COMPANY:	**MEDTRONIC SOFAMOR DANEK (MEDTSOFADANEA)**
PRODUCT:	**SPINAL VERTEBRAL BODY REPLACEMENT DEVICE (MQP)**
SUMMARY:	**Product: MODIFICATION TO VERTE-STACK SPINAL SYSTEM**

DATE REQUESTED:	**Tue Mar 25 24:00:00 2008**
DATE PRINTED:	**Thu Apr 10 10:54:30 2008**
Note:	**Releasable Version**

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NOV 16 2005

K052931

Page 1 of 2

VERTE-STACK® Spinal System
510(k) Summary
October 2005

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Richard W. Treharne**
Sr. Vice President 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 is a stackable spacer, which inserts between vertebral bodies in the anterior thoracic and lumbar spine. The device is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. The construct is not intended to be employed as a stand-alone device. The VERTE-STACK® device is fabricated and manufactured from POLYETHERETHERKETONE (PEEK OPTIMA LT1) along with either titanium or tantalum markers. Alternatively the entire device may be manufactured from titanium alloy.

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 must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK® constructs manufactured with 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 is to include slightly modified components to the previously cleared 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 Sofamor Danek ZPLATE II Anterior Fixation System, the DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, the GDLH® Spinal System and/or their successors. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

VI. Substantial Equivalence

Documentation was provided which demonstrated that the subject VERTE-STACK® Spinal System components are substantially equivalent to the previously cleared VERTE-STACK® Spinal System (K041197, SE 08/09/04 and K030736, SE 04/02/03).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2005

Dr. Richard W. Treharne
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K052931
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: October 14, 2005
Received: October 19, 2005

Dear Dr. Treharne:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K052931

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 Sofamor Danek ZPLATE II Anterior Fixation System, DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, the GDLH® Spinal System, or their successors. 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 K052931

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 11/17/05

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K052931/A1

To: Division Director: OR/DGRND

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____Additional information requires a new 510(k); however, the information submitted is incomplete: (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

X No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Sergio de del Castillo

Date: 11/18/05

DMC
11/21

Draft #2 : 9/8/99
Draft #3: 1/3/00
Draft #4: 3/7/03

K052931/A1

Medtronic

SOFAMOR DANEK

Regulatory Affairs Department

CONFIDENTIAL

November 15, 2005

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: 510(k): Additional Information VERTE-STACK® Spinal System – K052931

Dear Document Control Clerk:

On Nov. 15, 2005, we received an e-mail request from the reviewer regarding the above referenced 510(k) application. The reviewer's request appears in **bold** text, while our response follows in normal text.

1. **The Indications for Use are printed on an outdated form. Please provide the Indications of Use Statement on the current form, with the "Prescription Only" field checked, via email. Please also follow-up this request with a hard copy to the Document Mailing Center.**

   A corrected Indications of Use statement was e-mailed to the reviewer. Hard copies are included with this letter, per the reviewer's request.

We believe that this fully addresses the FDA's concerns regarding this submission. If you have any further questions regarding this submission, please telephone me at (901) 396-3133. You may also email questions to us at lgrant@sofamordanek.com or rtreharne@sofamordanek.com. 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.

Sincerely,

Richard W. Treharne

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Attachment

K-24
2

510(k) Number (if known): K052931

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 Sofamor Danek ZPLATE II Anterior Fixation System, DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, the GDLH® Spinal System, or their successors. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

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

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

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number (if known): K052931

Device Name: VERTE-STACK® Spinal System

Indications for Use:

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(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number (if known): K052931

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

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

_____

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2005

Dr. Richard W. Treharne
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K052931
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: October 14, 2005
Received: October 19, 2005

Dear Dr. Treharne:

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.

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Sincerely yours,

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

Enclosure

2

510(k) Number (if known): K052931

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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 K052931

3

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

October 19, 2005

MEDTRONIC SOFAMOR DANEK
PYRAMID PLACE
MEMPHIS, TN 38132
ATTN: RICHARD TREHARNE

510(k) Number: K052931
Received: 19-OCT-2005
Product: MODIFICATION TO VERTE-STACK SPINAL SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

On May 21, 2004, FDA issued a 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. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.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/oivd/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 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.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation

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K052931

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6022789-956733** Write the Payment Identification number on your check.

`mpleted Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken ıperly submit your application and fee payment:

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)

MEDTRONIC SOFAMOR DANEK
1800 PYRAMID PLACE
MEMPHIS TN 38132
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
621483635

2. CONTACT NAME
Richard Treharne

2.1 E-MAIL ADDRESS
rick.treharne@medtronic.com

2.2 TELEPHONE NUMBER (include Area code)
901-344-1124

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:
[X] Premarket notification(510(k)); except for third party
`iologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] 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.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] 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).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
$3,833.00 30-Sep-2005

Form FDA 8601 (08/2003)

`ıse Window

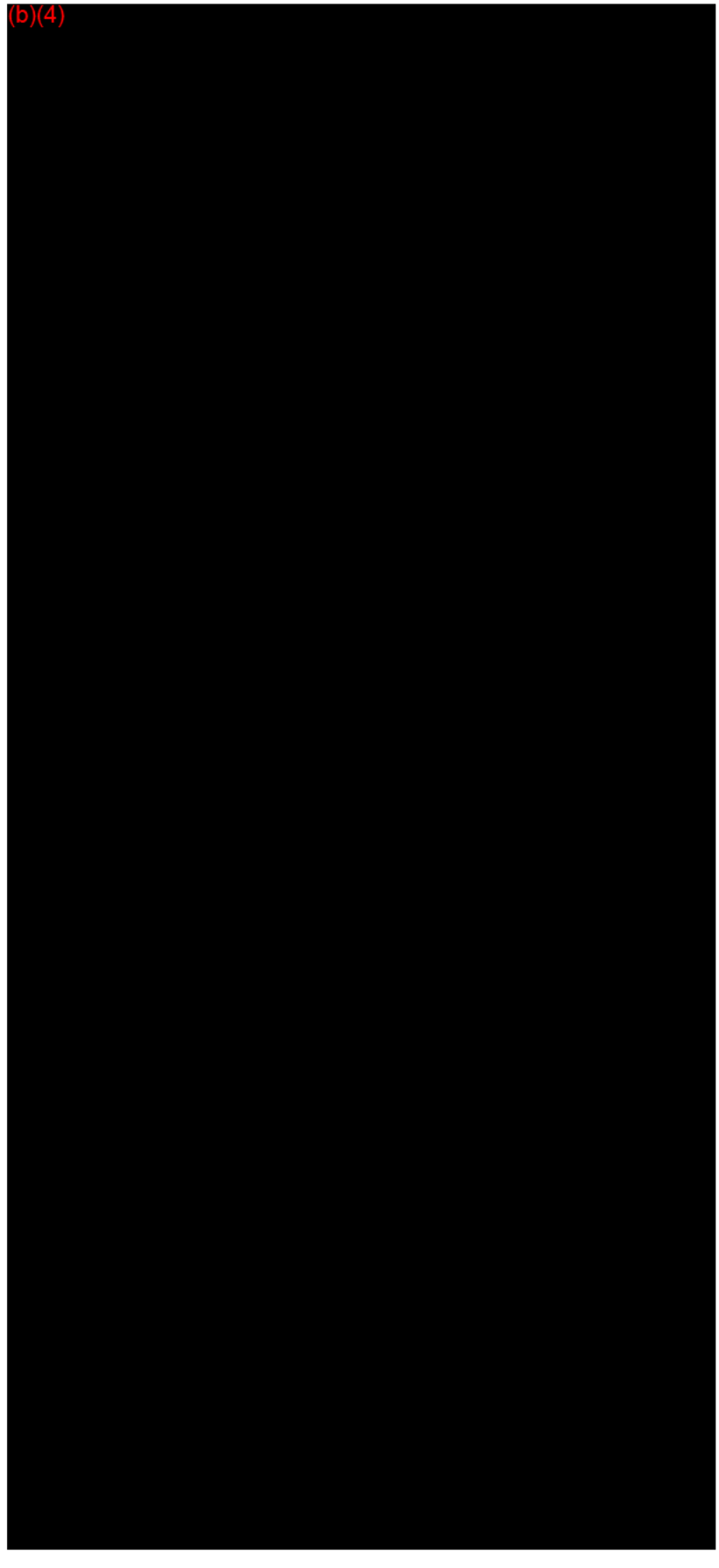
Print Cover sheet

OR II

K8

18

(b)(4)



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
10/18/2005		

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☑ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
Amendment	Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
Supplement	Supplement			
	Report			
	Report Amendment			

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: Pyramid Place	FAX Number *(including area code)*: (901) 346-9738		
City: Memphis	State / Province: TN	ZIP/Postal Code: 38132	Country: U.S.A.
Contact Name: Richard Treharne			
Contact Title: Sr. Vice President Regulatory Affairs	Contact E-mail Address: rtreharne@sofamordanek.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:		

PSC Media Arts (301) 443-1090 EF

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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

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

- [ ] Response to FDA correspondence:

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

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

- [ ] Location change:
  - Manufacturer
  - Sterilizer
  - Packager

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

- [ ] 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)

- [x] New Device
- [ ] Additional or Expanded Indications
- [ ] Change in Technology

- [x] Other Reason *(specify)*:

Modifying design

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1 MQP	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness information

- [ ] 510 (k) summary attached
- [ ] 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K041197	1	VERTE-STACK Spinal System	1	Medtronic Sofamor Danek
2	K030736	2	VERTE-STACK Spinal System	2	Medtronic Sofamor Danek
3	K031780	3	VERTE-STACK Spinal System	3	Medtronic Sofamor Danek
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Bone Fixation Appliance

	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 K041197	2 K030736	3 K031780	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

Classification Panel: General, Restorative and Neurologic Device

Device Class

- [ ] Class I
- [x] Class II
- [ ] Class III
- [ ] Unclassified

Indications *(from labeling)*

Please see attached labeling 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

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 1824199	☑ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*: Medtronic Sofamor Danek Warsaw (aka Warsaw Manufacturing)		Phone Number *(including area code)*: (901) 396-3133		
Street Address: 2500 Silveus Crossing		FAX Number *(including area code)*: ( )		
City: Warsaw		State / Province: IN	ZIP/Postal Code	Country
Contact Name: Rick Treharne	Contact Title: Sr. VP Regulatory Affairs		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
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	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
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 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

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
www.medtronic.com

t 901 396 3133
f 901 346 0738
cell 800 876 4133

October 14, 2005

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 (K041197)**

Dear Document Control Clerk:

The purpose of this **Special 510(k)** is to offer a slightly modified version of previously cleared VERTE-STACK® Spinal System components previously cleared by the FDA. From a regulatory point of view, we regard this device to be substantially equivalent[1] to itself.

Background

The VERTE-STACK® device consists of hemi-cylindrical center cages of various widths and heights, as well as hemi-cylindrical add on end pieces 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 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

[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 suites or other patent matters." (*Federal Register, Vol. 42, No. 163,* Aug. 23, 1977, page 42525 and 42529).

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VERTE-STACK® Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability.

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 devices. The fundamental scientific technology will remain unchanged.

(b)(4)

[redacted]

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.

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 K041197, K030736 and to K052261 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

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(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. (For reference only)

(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 titanium marker used for this product is made to the voluntary standard of ASTM F-136 or ISO 5832-3.

(f) Labeling

A sample label is provided in **Attachment 2** of this submission. A draft package insert is provided in **Attachment 3** of this submission. This labeling is identical to that provided in the previously cleared submission K052261.

"The electronic labeling 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 3** 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

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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 K041197, K030736 and K031780. 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)

[redacted]

Physical comparisons of the subject VERTE-STACK® Spinal System to the predicate device are provided in **Table 1**. As evidenced by the comparison table, the subject device is similar to the predicate device in terms of width, intended use and use with supplemental fixation.

Mechanical testing was also performed on the subject components with the results compared to those of the predicate VERTE-STACK® XS components cleared in K030736 and K041197. Worst-case constructs were determined to be the device consisting of the largest construct with the smallest footprint. The 25mm x 11mm x 11mm centerpiece possesses the smallest footprint, and when paired with the 13mm end caps, this creates the largest possible construct with the smallest footprint.

Dynamic compression fatigue testing was performed in accordance with the FDA Guidance for Spinal System (May 3, 2004). For vertebral body replacement devices, the guidance states that, "For the dynamic axial compression bending tests, we recommend that you meet one of the following conditions:

• asymptotic load level >=3000N (~2x the vertebral body compression strength) at 5 x 10^6 cycles

• asymptotic load level >=1500N (~1x the vertebral body compression strength) at 10 x 10^6 cycles"

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(b)(4)

[redacted]

Torsional test results are also included in the referenced test report.

(b)(4)

[redacted]

This is done in accordance with the following standards:

ANSI/AAMI/ISO 11137: Sterilization of health care products – Requirements for validation and routine control.

ANSI/AAMI/ISO/ TR 13409: Sterilization of health care products – Radiation sterilization – Substantiation of 2 kGy as a sterilization dose for small or infrequent products batches.

DIN EN 552 Sterilization of medical devices – Validation and routine control sterilization by irradiation 2001

Table 1 Comparison of Predicate and Subject VERTE-STACK® Spinal System

Features	Predicate Device (K041197/K030736/K031780) VERTE-STACK® Spinal System	Subject VERTE-STACK® Device
Sterilization	Gamma Sterilized	Identical
Material	PEEK Optima LT1 and Titanium	Identical
Supplemental fixation required	Yes	Identical
Intended use	Vertebral body replacement to aid in the surgical correction and stabilization of the spine.	Identical
Stackable	Yes	Identical
Center Piece Size Range	5mm –25mm height (K030736); 8mm-52mm (K031780)	6mm - 25mm height
End Piece Size Range	4mm x 11mm x 11mm – 13mm x 14mm x 14mm	5mm x 11mm x 11mm – 13mm x 14mm x 14mm
(b)(4) [redacted]	None	(b)(4) [redacted]

(h) Safety and Effectiveness

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The VERTE-STACK® Spinal System components included in this submission are substantially equivalent to those previously cleared in K041197. 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 4**.

(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.

(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 VERTE-STACK® Spinal System components is provided in **Attachment 5** of this submission. The previously cleared VERTE-STACK® components appear in regular text while the subject components are noted in **bold** text. Also included 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® components are provided in **Attachment 6** of this submission.

Indications Statement

In compliance with the form required after January 1, 1996, **Attachment 7** 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.

If you have any questions regarding this submission, please call Lee Grant or me at (901) 396-3133. You may also email questions to Lee Grant at lgrant@sofamordanek.com or to me at rtreharne@sofamordanek.com.

Sincerely,

Richard W. Treharne

Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Attachments

Medtronic
SOFAMOR DANEK

Regulatory Affairs Department

Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, TN 38132
www.medtronic.com

tel 901 396 3133
fax 901 396 0738
toll 800 876 4133

Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Senior Vice President 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.

Richard W. Treharne 17 Oct 05

Richard W. Treharne, Ph.D. Date
Senior Vice President Regulatory Affairs

*(Premarket Notification [510(k)] Number

*For a new submission, leave the 510(k) number blank.

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Attachment 1

Declaration of Conformity with Design Controls

Risk Analysis and Test Report

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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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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.

Carl Stamp — 10-14-05

Carl Stamp — Date

Vice President, Trauma

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 — 10/17/05

Tom Slagle — Date

Senior Manager, Quality Engineering

000010

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(b)(4) Pages 36-86 testing

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Attachment 2

Sample Label

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Sample Label

Medtronic
SOFAMOR DANEK

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

EC Representative
Medtronic B.V.
Earl Bakkenstraat 10
6422 P J Heerlen
The Netherlands
Tel: + 31 45 566 80 00

LOT TEST

REF: 6286511
VERTE-STACK® Spinal System
VERTE-STACK® Extra Small End Piece
Size: Extra Small – 5mm x 11mm x 11mm
MAT'L: PEEK OPTIMA LT

UCC: (01)00673978049182(10)TEST

QTY 1 EA
STERILE

Manufactured at: Warsaw, Indiana USA

Rx only

CE 0123

000002

89

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Attachment 3

Draft Package Insert

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 MSD 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 Sofamor Danek spinal systems or their successors must be used with the VERTE-STACK® Spinal System.

	Anterior	Posterior
ZPLATE-II® Anterior Fixation System	√	
DYNALOK® CLASSIC Spinal System	√	√
VANTAGE® Anterior Fixation System	√	
TSRH® Spinal System	√	√
CD HORIZON® Spinal System	√	√

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 Sofamor Danek ZPLATE II Anterior Fixation System, the DYNALOK® 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. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
9. Suspected or documented metal allergy or intolerance.
10. Any case needing to mix metals from different components.
11. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
12. Any case not described in the indications.
13. Any patient unwilling to co-operate with postoperative instructions.
14. 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.

Possible Adverse Effects:
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 neurologial 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 Sofamor Danek 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, the important medical information given in this document should be conveyed to the patient.

PATIENT INFORMATION: The internal fixation device used in your recent spinal surgery is a plastic polymer implant that attaches to the bone and aids in the healing of bone grafts. 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 level and two-level anterior use from T1 to L5 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 Sofamor Danek. 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 Sofamor Danek.

Cleaning and Decontamination: Unless just removed from an unopened Medtronic Sofamor Danek 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 Sofamor Danek. 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 Sofamor Danek 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 three sets of process parameters below:

(b)(4) [redacted]

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 Sofamor Danek. 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 Sofamor Danek 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:

IN THE USA
Customer Service DivisionTele: 800-876-3133
Medtronic Sofamor Danek or 901-396-3133
1800 Pyramid Place Telefax: 901-396-0356
Memphis, TN 38132 USA or 901-332-3920

IN EUROPE
Medtronic B.V.
Earl Bakkenstraat 10
6422 P J Herleen
The Netherlands
Tel: + 31 45 566 80 00

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Attachment 4

510(k) Summary

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VERTE-STACK® Spinal System
510(k) Summary
October 2005

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

Contact: **Richard W. Treharne**
Sr. Vice President 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 is a stackable spacer, which inserts between vertebral bodies in the anterior thoracic and lumbar spine. The device is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. The construct is not intended to be employed as a stand-alone device. The VERTE-STACK® device is fabricated and manufactured from POLYETHERETHERKETONE (PEEK OPTIMA LT1) along with either titanium or tantalum markers. Alternatively the entire device may be manufactured from titanium alloy.

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 must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK® constructs manufactured with 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 is to include slightly modified components to the previously cleared 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 Sofamor Danek ZPLATE II Anterior Fixation System, the DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, the GDLH® Spinal System and/or their successors. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

VI. Substantial Equivalence

Documentation was provided which demonstrated that the subject VERTE-STACK® Spinal System components are substantially equivalent to the previously cleared VERTE-STACK® Spinal System (K041197, SE 08/09/04 and K030736, SE 04/02/03).

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Attachment 5

Implant and Instrument List

VERTE-STACK® Spinal System Implant Table

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® XS Center Piece 6mm X 11mm X 11mm	**6276006**	**T/L**	**NEW**
VERTE-STACK® XS Center Piece 25mm X 11mm X 11mm	**6276025**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 5mm X 11mm X 11mm	**6286511**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 6mm X 11mm X 11mm	**6286611**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 7mm X 11mm X 11mm	**6286711**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 8mm X 11mm X 11mm	**6286811**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 9mm X 11mm X 11mm	**6286911**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 10mm X 11mm X 11mm	**6286011**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 11mm X 11mm X 11mm	**6286111**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 12mm X 11mm X 11mm	**6286211**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 13mm X 11mm X 11mm	**6286311**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 5mm X 14mm X 11mm	**6287541**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 6mm X 14mm X 11mm	**6287641**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 7mm X 14mm X 11mm	**6287741**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 8mm X 14mm X 11mm	**6287841**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 9mm X 14mm X 11mm	**6287941**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 10mm X 14mm X 11mm	**6287041**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 11mm X 14mm X 11mm	**6287141**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 12mm X 14mm X 11mm	**6287241**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 13mm X 14mm X 11mm	**6287341**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 5mm X 14mm X 14mm	**6287541**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 6mm X 14mm X 14mm	**6287641**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 7mm X 14mm X 14mm	**6287741**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 8mm X 14mm X 14mm	**6287841**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 9mm X 14mm X 14mm	**6287941**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 10mm X 14mm X 14mm	**6287041**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 11mm X 14mm X 14mm	**6287141**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 12mm X 14mm X 14mm	**6287241**	**T/L**	**NEW**
VERTE-STACK® XS End Piece 13mm X 14mm X 14mm	**6287341**	**T/L**	**NEW**
VERTE-STACK® Crescent End Piece 25mm x 8mm	9192508	T/L	K052261
VERTE-STACK® Crescent End Piece 25mm x 9mm	9192509	T/L	K052261
VERTE-STACK® Crescent End Piece 25mm x 10mm	9192510	T/L	K052261
VERTE-STACK® Crescent End Piece 25mm x 11mm	9192511	T/L	K052261
VERTE-STACK® Crescent End Piece 25mm x 12mm	9192512	T/L	K052261
VERTE-STACK® Crescent End Piece 25mm x 13mm	9192513	T/L	K052261
VERTE-STACK® Crescent End Piece 25mm x 14mm	9192514	T/L	K052261
VERTE-STACK® Crescent End Piece 25mm x 15mm	9192515	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 7mm	9193007	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 8mm	9193008	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 9mm	9193009	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 10mm	9193010	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 11mm	9193011	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 12mm	9193012	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 13mm	9193013	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 14mm	9193014	T/L	K052261
VERTE-STACK® Crescent End Piece 30mm x 15mm	9193015	T/L	K052261
VERTE-STACK® Crescent End Piece 36mm x 7mm	9193607	T/L	K052261
VERTE-STACK® Crescent End Piece 36mm x 8mm	9193608	T/L	K052261
VERTE-STACK® Crescent End Piece 36mm x 9mm	9193609	T/L	K052261

[1] All implants may be sold individually.

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® Crescent End Piece 36mm x 10mm	9193610	T/L	K052261
VERTE-STACK® Crescent End Piece 36mm x 11mm	9193611	T/L	K052261
VERTE-STACK® Crescent End Piece 36mm x 12mm	9193612	T/L	K052261
VERTE-STACK® Crescent End Piece 36mm x 13mm	9193613	T/L	K052261
VERTE-STACK® Crescent End Piece 36mm x 14mm	9193614	T/L	K052261
VERTE-STACK® Crescent Centerpiece 25mm x 40mm	4260502	T/L	K052261
CAPSTONE™ VERTE-STACK TI VBS END 8 X 22mm	2970822	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 8 X 26mm	2970826	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 8 X 32mm	2970832	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 8 X 36mm	2970836	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 10 X 22mm	2971022	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 10 X 26mm	2971026	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 10 X 32mm	2971032	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 10 X 36mm	2971036	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 12 X 22mm	2971222	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 12 X 26mm	2971226	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 12 X 32mm	2971232	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 12 X 36mm	2971236	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 14 X 22mm	2971422	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 14 X 26mm	2971426	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 14 X 32mm	2971432	T/L	K043561
CAPSTONE™ VERTE-STACK TI VBS END 14 X 36mm	2971436	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 46.4mm height	3003646	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 44.4mm height	3003644	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 42.4mm height	3003642	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 40.4mm height	3003640	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 38.4mm height	3003638	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 36.4mm height	3003636	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 34.4mm height	3003634	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 32.4mm height	3003632	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 46.4mm height	3003246	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 44.4mm height	3003244	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 42.4mm height	3003242	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 40.4mm height	3003240	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 38.4mm height	3003238	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 36.4mm height	3003236	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 34.4mm height	3003234	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 32.4mm height	3003232	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 46.4mm height	3002646	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 44.4mm height	3002644	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 42.4mm height	3002642	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 40.4mm height	3002640	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 38.4mm height	3002638	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 36.4mm height	3002636	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 34.4mm height	3002634	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 32.4mm height	3002632	T/L	K043561

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
12mm Ti CENTER PIECE 22mm length x 46.4mm height	3002246	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 44.4mm height	3002245	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 42.4mm height	3002242	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 40.4mm height	3002240	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 38.4mm height	3002238	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 36.4mm height	3002236	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 34.4mm height	3002234	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 32.4mm height	3002232	T/L	K043561
8mm Ti CENTER PIECE 36mm length x 14.4mm height	3003614	T/L	K043561
8mm Ti CENTER PIECE 36mm length x 12.4mm height	3003612	T/L	K043561
8mm Ti CENTER PIECE 36mm length x 10.4mm height	3003610	T/L	K043561
8mm Ti CENTER PIECE 32mm length x 14.4mm height	3003214	T/L	K043561
8mm Ti CENTER PIECE 32mm length x 12.4mm height	3003212	T/L	K043561
8mm Ti CENTER PIECE 32mm length x 10.4mm height	3003210	T/L	K043561
8mm Ti CENTER PIECE 26mm length x 14.4mm height	3002614	T/L	K043561
8mm Ti CENTER PIECE 26mm length x 12.4mm height	3002612	T/L	K043561
8mm Ti CENTER PIECE 26mm length x 10.4mm height	3002610	T/L	K043561
8mm Ti CENTER PIECE 22mm length x 14.4mm height	3002214	T/L	K043561
8mm Ti CENTER PIECE 22mm length x 12.4mm height	3002212	T/L	K043561
8mm Ti CENTER PIECE 22mm length x 10.4mm height	3002210	T/L	K043561
10mm Ti CENTER PIECE 36mm length x 30.4mm height	3003630	T/L	K043561
10mm Ti CENTER PIECE 36mm length x 28.4mm height	3003628	T/L	K043561
10mm Ti CENTER PIECE 36mm length x 26.4mm height	3003626	T/L	K043561
10mm Ti CENTER PIECE 36mm length x 24.4mm height	3003624	T/L	K043561
10mm Ti CENTER PIECE 36mm length x 22.4mm height	3003622	T/L	K043561
10mm Ti CENTER PIECE 36mm length x 20.4mm height	3003620	T/L	K043561
10mm Ti CENTER PIECE 36mm length x 18.4mm height	3003618	T/L	K043561
10mm Ti CENTER PIECE 36mm length x 16.4mm height	3003616	T/L	K043561
10mm Ti CENTER PIECE 32mm length x 30.4mm height	3003230	T/L	K043561
10mm Ti CENTER PIECE 32mm length x 28.4mm height	3003228	T/L	K043561
10mm Ti CENTER PIECE 32mm length x 26.4mm height	3003226	T/L	K043561
10mm Ti CENTER PIECE 32mm length x 24.4mm height	3003224	T/L	K043561
10mm Ti CENTER PIECE 32mm length x 22.4mm height	3003222	T/L	K043561
10mm Ti CENTER PIECE 32mm length x 20.4mm height	3003220	T/L	K043561
10mm Ti CENTER PIECE 32mm length x 18.4mm height	3003218	T/L	K043561
10mm Ti CENTER PIECE 32mm length x 16.4mm height	3003216	T/L	K043561
10mm Ti CENTER PIECE 26mm length x 30.4mm height	3002630	T/L	K043561
10mm Ti CENTER PIECE 26mm length x 28.4mm height	3002628	T/L	K043561
10mm Ti CENTER PIECE 26mm length x 26.4mm height	3002626	T/L	K043561
10mm Ti CENTER PIECE 26mm length x 24.4mm height	3002624	T/L	K043561
10mm Ti CENTER PIECE 26mm length x 22.4mm height	3002622	T/L	K043561
10mm Ti CENTER PIECE 26mm length x 20.4mm height	3002620	T/L	K043561
10mm Ti CENTER PIECE 26mm length x 18.4mm height	3002618	T/L	K043561
10mm Ti CENTER PIECE 26mm length x 16.4mm height	3002616	T/L	K043561
10mm Ti CENTER PIECE 22mm length x 30.4mm height	3002230	T/L	K043561
10mm Ti CENTER PIECE 22mm length x 28.4mm height	3002228	T/L	K043561

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
10mm Ti CENTER PIECE 22mm length x 26.4mm height	3002226	T/L	K043561
10mm Ti CENTER PIECE 22mm length x 24.4mm height	3002224	T/L	K043561
10mm Ti CENTER PIECE 22mm length x 22.4mm height	3002222	T/L	K043561
10mm Ti CENTER PIECE 22mm length x 20.4mm height	3002220	T/L	K043561
10mm Ti CENTER PIECE 22mm length x 18.4mm height	3002218	T/L	K043561
10mm Ti CENTER PIECE 22mm length x 16.4mm height	3002216	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 46.4mm height	3003646	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 44.4mm height	3003644	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 42.4mm height	3003642	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 40.4mm height	3003640	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 38.4mm height	3003638	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 36.4mm height	3003636	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 34.4mm height	3003634	T/L	K043561
12mm Ti CENTER PIECE 36mm length x 32.4mm height	3003632	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 46.4mm height	3003246	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 44.4mm height	3003244	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 42.4mm height	3003242	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 40.4mm height	3003240	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 38.4mm height	3003238	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 36.4mm height	3003236	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 34.4mm height	3003234	T/L	K043561
12mm Ti CENTER PIECE 32mm length x 32.4mm height	3003232	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 46.4mm height	3002646	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 44.4mm height	3002644	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 42.4mm height	3002642	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 40.4mm height	3002640	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 38.4mm height	3002638	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 36.4mm height	3002636	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 34.4mm height	3002634	T/L	K043561
12mm Ti CENTER PIECE 26mm length x 32.4mm height	3002632	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 46.4mm height	3002246	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 44.4mm height	3002245	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 42.4mm height	3002242	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 40.4mm height	3002240	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 38.4mm height	3002238	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 36.4mm height	3002236	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 34.4mm height	3002234	T/L	K043561
12mm Ti CENTER PIECE 22mm length x 32.4mm height	3002232	T/L	K043561
14mm Ti CENTER PIECE 36mm length x 54.4mm height	3003654	T/L	K043561
14mm Ti CENTER PIECE 36mm length x 52.4mm height	3003652	T/L	K043561
14mm Ti CENTER PIECE 36mm length x 50.4mm height	3003650	T/L	K043561
14mm Ti CENTER PIECE 36mm length x 48.4mm height	3003648	T/L	K043561
14mm Ti CENTER PIECE 32mm length x 54.4mm height	3003254	T/L	K043561
14mm Ti CENTER PIECE 32mm length x 52.4mm height	3003252	T/L	K043561
14mm Ti CENTER PIECE 32mm length x 50.4mm height	3003250	T/L	K043561
14mm Ti CENTER PIECE 32mm length x 48.4mm height	3003248	T/L	K043561

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
14mm Ti CENTER PIECE 26mm length x 54.4mm height	3002654	T/L	K043561
14mm Ti CENTER PIECE 26mm length x 52.4mm height	3002652	T/L	K043561
14mm Ti CENTER PIECE 26mm length x 50.4mm height	3002650	T/L	K043561
14mm Ti CENTER PIECE 26mm length x 48.4mm height	3002648	T/L	K043561
14mm Ti CENTER PIECE 22mm length x 54.4mm height	3002254	T/L	K043561
14mm Ti CENTER PIECE 22mm length x 52.4mm height	3002252	T/L	K043561
14mm Ti CENTER PIECE 22mm length x 50.4mm height	3002250	T/L	K043561
14mm Ti CENTER PIECE 22mm length x 48.4mm height	3002248	T/L	K043561
VERTE-STACK® End Piece 4mmx11mmx11mm	6276411	T/L	K041197
VERTE-STACK® End Piece 5mmx11mmx11mm	6276511	T/L	K041197
VERTE-STACK® End Piece 6mmx11mmx11mm	6276611	T/L	K041197
VERTE-STACK® End Piece 7mmx11mmx11mm	6276711	T/L	K041197
VERTE-STACK® End Piece 8mmx11mmx11mm	6276811	T/L	K041197
VERTE-STACK® End Piece 9mmx11mmx11mm	6276911	T/L	K041197
VERTE-STACK® End Piece 10mmx11mmx11mm	6276011	T/L	K041197
VERTE-STACK® End Piece 11mmx11mmx11mm	6276111	T/L	K041197
VERTE-STACK® End Piece 12mmx11mmx11mm	6276211	T/L	K041197
VERTE-STACK® End Piece 13mmx11mmx11mm	6276311	T/L	K041197
VERTE-STACK® End Piece 4mmx14mmx11mm	6277441	T/L	K041197
VERTE-STACK® End Piece 5mmx14mmx11mm	6277541	T/L	K041197
VERTE-STACK® End Piece 6mmx14mmx11mm	6277641	T/L	K041197
VERTE-STACK® End Piece 7mmx14mmx11mm	6277741	T/L	K041197
VERTE-STACK® End Piece 8mmx14mmx11mm	6277841	T/L	K041197
VERTE-STACK® End Piece 9mmx14mmx11mm	6277941	T/L	K041197
VERTE-STACK® End Piece 10mmx14mmx11mm	6277041	T/L	K041197
VERTE-STACK® End Piece 11mmx14mmx11mm	6277141	T/L	K041197
VERTE-STACK® End Piece 12mmx14mmx11mm	6277241	T/L	K041197
VERTE-STACK® End Piece 13mmx14mmx11mm	6277341	T/L	K041197
VERTE-STACK® End Piece 4mmx14mmx14mm	6278444	T/L	K041197
VERTE-STACK® End Piece 5mmx14mmx14mm	6278544	T/L	K041197
VERTE-STACK® End Piece 6mmx14mmx14mm	6278644	T/L	K041197
VERTE-STACK® End Piece 7mmx14mmx14mm	6278744	T/L	K041197
VERTE-STACK® End Piece 8mmx14mmx14mm	6278844	T/L	K041197
VERTE-STACK® End Piece 9mmx14mmx14mm	6278944	T/L	K041197
VERTE-STACK® End Piece 10mmx14mmx14mm	6278044	T/L	K041197
VERTE-STACK® End Piece 11mmx14mmx14mm	6278144	T/L	K041197
VERTE-STACK® End Piece 12mmx14mmx14mm	6278244	T/L	K041197
VERTE-STACK® End Piece 13mmx14mmx14mm	6278344	T/L	K041197
VERTE-STACK® CAPSTONE End Piece 8mm X 22mm	2960822	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 8mm X 26mm	2960826	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 8mm X 32mm	2960832	T/L	K041556

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® CAPSTONE End Piece 8mm X 36mm	2960836	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 10mm X 22mm	2961022	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 10mm X 26mm	2961026	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 10mm X 32mm	2961032	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 10mm X 36mm	2961036	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 12mm X 22mm	2961222	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 12mm X 26mm	2961226	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 12mm X 32mm	2961232	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 12mm X 36mm	2961236	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 14mm X 22mm	2961422	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 14mm X 26mm	2961426	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 14mm X 32mm	2961432	T/L	K041556
VERTE-STACK® CAPSTONE End Piece 14mm X 36mm	2961436	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 10mm X 22mm	2992210	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 12mm X 22mm	2992212	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 14mm X 22mm	2992214	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 10mm X 26mm	2992610	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 12mm X 26mm	2992612	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 14mm X 26mm	2992614	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 10mm X 32mm	2993210	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 12mm X 32mm	2993212	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 14mm X 32mm	2993214	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 10mm X 36mm	2993610	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 12mm X 36mm	2993612	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 8mm X 14mm X 36mm	2993614	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 16mm X 22mm	2992216	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 18mm X 22mm	2992218	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 20mm X 22mm	2992220	T/L	K041556

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® CAPSTONE Center Piece 10mm X 22mm X 22mm	2992222	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 24mm X 22mm	2992224	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 26mm X 22mm	2992226	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 28mm X 22mm	2992228	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 30mm X 22mm	2992230	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 16mm X 26mm	2992616	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 18mm X 26mm	2992618	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 20mm X 26mm	2992620	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 22mm X 26mm	2992622	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 24mm X 26mm	2992624	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 26mm X 26mm	2992626	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 28mm X 26mm	2992628	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 30mm X 26mm	2992630	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 16mm X 32mm	2993216	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 18mm X 32mm	2993218	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 20mm X 32mm	2993220	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 22mm X 32mm	2993222	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 24mm X 32mm	2993224	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 26mm X 26mm	2993226	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 28mm X 32mm	2993228	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 30mm X 32mm	2993230	T/L	K041556
VERTE-STACK ®CAPSTONE Center Piece 10mm X 16mm X 36mm	2993616	T/L	K041556

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® CAPSTONE Center Piece 10mm X 18mm X 36mm	2993618	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 20mm X 36mm	2993620	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 22mm X 36mm	2993622	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 24mm X 36mm	2993624	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 26mm X 36mm	2993626	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 28mm X 36mm	2993628	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 10mm X 30mm X 36mm	2993630	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 32mm X 22mm	2992232	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 34mm X 22mm	2992234	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 36mm X 22mm	2992236	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 38mm X 22mm	2992238	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 40mm X 22mm	2992240	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 42mm X 22mm	2992242	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 44mm X 22mm	2992244	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 46mm X 22mm	2992246	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 32mm X 26mm	2992632	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 34mm X 26mm	2992634	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 36mm X 26mm	2992636	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 38mm X 26mm	2992638	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 40mm X 26mm	2992640	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 42mm X 26mm	2992642	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 44mm X 26mm	2992644	T/L	K041556

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® CAPSTONE Center Piece 12mm X 46mm X 26mm	2992646	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 32mm X 32mm	2993232	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 34mm X 32mm	2993234	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 36mm X 32mm	2993236	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 38mm X 32mm	2993238	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 40mm X 32mm	2993240	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 42mm X 32mm	2993242	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 44mm X 32mm	2993244	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 46mm X 32mm	2993246	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 32mm X 36mm	2993332	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 34mm X 36mm	2993634	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 36mm X 36mm	2993636	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 38mm X 36mm	2993638	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 40mm X 36mm	2993640	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 42mm X 36mm	2993642	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 44mm X 36mm	2993644	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 12mm X 46mm X 36mm	2993646	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 48mm X 22mm	2992248	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 50mm X 22mm	2992250	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 52mm X 22mm	2992252	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 54mm X 22mm	2992254	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 48mm X 26mm	2992648	T/L	K041556

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® CAPSTONE Center Piece 14mm X 50mm X 26mm	2992650	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 52mm X 26mm	2992652	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 54mm X 26mm	2992654	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 48mm X 32mm	2993248	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 50mm X 32mm	2993250	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 52mm X 32mm	2993252	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 54mm X 32mm	2993254	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 48mm X 36mm	2993648	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 50mm X 36mm	2993650	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 52mm X 36mm	2993652	T/L	K041556
VERTE-STACK® CAPSTONE Center Piece 14mm X 54mm X 36mm	2993654	T/L	K041556
VERTE-STACK® BOOMERANG End Piece 6mm X 25mm	9192106	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 7mm X 25mm	9192107	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 8mm X 25mm	9192108	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 9mm X 25mm	9192109	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 10mm X 25mm	9192110	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 11mm X 25mm	9192111	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 12mm X 25mm	9192112	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 13mm X 25mm	9192113	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 14mm X 25mm	9192114	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 15mm X 25mm	9192115	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 7mm X 30mm	9192207	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 8mm X 30mm	9192208	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 9mm X 30mm	9192209	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 10mm X 30mm	9192210	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 11mm X 30mm	9192211	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 12mm X 30mm	9192212	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 13mm X 30mm	9192213	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 14mm X 30mm	9192214	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 15mm X 30mm	9192215	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 16mm X 30mm	9192216	T/L	K040536

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® BOOMERANG End Piece 17mm X 30mm	9192217	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 18mm X 30mm	9192218	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 7mm X 36mm	9192307	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 8mm X 36mm	9192308	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 9mm X 36mm	9192309	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 10mm X 36mm	9192310	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 11mm X 36mm	9192311	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 12mm X 36mm	9192312	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 13mm X 36mm	9192313	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 14mm X 36mm	9192314	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 15mm X 36mm	9192315	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 16mm X 36mm	9192316	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 17mm X 36mm	9192317	T/L	K040536
VERTE-STACK® BOOMERANG End Piece 18mm X 36mm	9192318	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 25mm X 10mm	9192130	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 25mm X 20mm	9192131	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 25mm X 40mm	9192132	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 30mm X 10mm	9192230	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 30mm X 20mm	9192231	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 30mm X 40mm	9192232	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 36mm X 10mm	9192330	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 36mm X 20mm	9192331	T/L	K040536
VERTE-STACK® Strutless (SL) Centerpiece 36mm X 40mm	9192332	T/L	K040536
VERTE-STACK® Telamon Titanium End Piece 3° 22 x 8mm	4182208	T/L	K040422
VERTE-STACK® Telamon Titanium End Piece 3° 22 x10mm	4182210	T/L	K040422
VERTE-STACK® Telamon Titanium End Piece 3° 22 x 12mm	4182212	T/L	K040422
VERTE-STACK® Telamon Titanium End Piece 3° 22 x 14mm	4182214	T/L	K040422
VERTE-STACK® Telamon Titanium End Piece 3° 26 x 8mm	4182608	T/L	K040422
VERTE-STACK® Telamon Titanium End Piece 3° 26 x 10mm	4182610	T/L	K040422
VERTE-STACK® Telamon Titanium End Piece 3° 26 x 12mm	4182612	T/L	K040422
VERTE-STACK® Telamon Titanium End Piece 3° 26 x 14mm	4182614	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 8mm	4282208	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 10mm	4282210	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 12mm	4282212	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 14mm	4282214	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 16mm	4282216	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 18mm	4282218	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 20mm	4282220	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 22mm	4282222	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 24mm	4282224	T/L	K040422

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® Telamon Titanium 3° Center 22mm x 26mm	4282226	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 28mm	4282228	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 30mm	4282230	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 32mm	4282232	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 34mm	4282234	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 36mm	4282236	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 38mm	4282238	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 40mm	4282240	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 42mm	4282242	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 44mm	4282244	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 46mm	4282246	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 48mm	4282248	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 50mm	4282250	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 22mm x 52mm	4282252	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 08mm	4282608	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 10mm	4282610	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 12mm	4282612	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 14mm	4282614	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 16mm	4282616	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 18mm	4282618	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 20mm	4282620	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 22mm	4282622	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 24mm	4282624	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 26mm	4282626	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 28mm	4282628	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 30mm	4282630	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 32mm	4282632	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 34mm	4282634	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 36mm	4282636	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 38mm	4282638	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 40mm	4282640	T/L	K040422
VERTE-STACK® Telamon Titanium 3° Center 26mm x 42mm	4282642	T/L	K040422
VERTE-STACK® Telamon Ti 3° Center 26mm x 44mm	4282644	T/L	K040422
VERTE-STACK® Telamon Ti 3° Center 26mm x 46mm	4282646	T/L	K040422
VERTE-STACK® Telamon Ti 3° Center 26mm x 48mm	4282648	T/L	K040422
VERTE-STACK® Telamon Ti 3° Center 26mm x 50mm	4282650	T/L	K040422
VERTE-STACK® Telamon Ti 3° Center 26mm x 52mm	4282652	T/L	K040422
VERTE-STACK® VBS End 0° 22 x 8mm	4302208	T/L	K031780
VERTE-STACK® VBS End 0° 22 x 10mm	4302210	T/L	K031780
VERTE-STACK® VBS End 0° 22 x 12mm	4302212	T/L	K031780

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® VBS End 0° 22 x 14mm	4302214	T/L	K031780
VERTE-STACK® VBS End 0° 26 x 8	4302608	T/L	K031780
VERTE-STACK® VBS End 0° 26 x 10mm	4302610	T/L	K031780
VERTE-STACK® VBS End 0° 26 x 12mm	4302612	T/L	K031780
VERTE-STACK® VBS End 0° 26 x 14mm	4302614	T/L	K031780
VERTE-STACK® VBS End 3° 22 x 8mm	4332208	T/L	K031780
VERTE-STACK® VBS End 3° 22 x10mm	4332210	T/L	K031780
VERTE-STACK® VBS End 3° 22 x 12mm	4332212	T/L	K031780
VERTE-STACK® VBS End 3° 22 x 14mm	4332214	T/L	K031780
VERTE-STACK® VBS End 3° 26 x 8mm	4332608	T/L	K031780
VERTE-STACK® VBS End 3° 26 x 10mm	4332610	T/L	K031780
VERTE-STACK® VBS End 3° 26 x 12mm	4332612	T/L	K031780
VERTE-STACK® VBS End 3° 26 x 14mm	4332614	T/L	K031780
VERTE-STACK® 0° Center 22mm x 8mm	4402208	T/L	K031780
VERTE-STACK® 0° Center 22mm x 10mm	4402210	T/L	K031780
VERTE-STACK® 0° Center 22mm x 12mm	4402212	T/L	K031780
VERTE-STACK® 0° Center 22mm x 14mm	4402214	T/L	K031780
VERTE-STACK® 0° Center 22mm x 16mm	4402216	T/L	K031780
VERTE-STACK® 0° Center 22mm x 18mm	4402218	T/L	K031780
VERTE-STACK® 0° Center 22mm x 20mm	4402220	T/L	K031780
VERTE-STACK® 0° Center 22mm x 22mm	4402222	T/L	K031780
VERTE-STACK® 0° Center 22mm x 24mm	4402224	T/L	K031780
VERTE-STACK® 0° Center 22mm x 26mm	4402226	T/L	K031780
VERTE-STACK® 0° Center 22mm x 28mm	4402228	T/L	K031780
VERTE-STACK® 0° Center 22mm x 30mm	4402230	T/L	K031780
VERTE-STACK® 0° Center 22mm x 32mm	4402232	T/L	K031780
VERTE-STACK® 0° Center 22mm x 34mm	4402234	T/L	K031780
VERTE-STACK® 0° Center 22mm x 36mm	4402236	T/L	K031780
VERTE-STACK® 0° Center 22mm x 38mm	4402238	T/L	K031780
VERTE-STACK™ 0° Center 22mm x 40mm	4402240	T/L	K031780
VERTE-STACK™ 0° Center 22mm x 42mm	4402242	T/L	K031780
VERTE-STACK™ 0° Center 22mm x 44mm	4402244	T/L	K031780
VERTE-STACK™ 0° Center 22mm x 46mm	4402246	T/L	K031780
VERTE-STACK™ 0° Center 22mm x 48mm	4402248	T/L	K031780
VERTE-STACK™ 0° Center 22mm x 50mm	4402250	T/L	K031780
VERTE-STACK™ 0° Center 22mm x 52mm	4402252	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 08mm	4402608	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 10mm	4402610	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 12mm	4402612	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 14mm	4402614	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 16mm	4402616	T/L	K031780

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK™ 0° Center 26mm x 18mm	4402618	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 20mm	4402620	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 22mm	4402622	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 24mm	4402624	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 26mm	4402626	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 28mm	4402628	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 30mm	4402630	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 32mm	4402632	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 34mm	4402634	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 36mm	4402636	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 38mm	4402638	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 40mm	4402640	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 42mm	4402642	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 44mm	4402644	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 46mm	4402646	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 48mm	4402648	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 50mm	4402650	T/L	K031780
VERTE-STACK™ 0° Center 26mm x 52mm	4402652	T/L	K031780
VERTE-STACK™ 3° Center 22mm x 8mm	4432208	T/L	K031780
VERTE-STACK™ 3° Center 22mm x 10mm	4432210	T/L	K031780
VERTE-STACK™ 3° Center 22mm x 12mm	4432212	T/L	K031780
VERTE-STACK™ 3° Center 22mm x 14mm	4432214	T/L	K031780
VERTE-STACK™ 3° Center 22mm x 16mm	4432216	T/L	K031780
VERTE-STACK™ 3° Center 22mm x 18mm	4432218	T/L	K031780
VERTE-STACK®3° Center 22mm x 20mm	4432220	T/L	K031780
VERTE-STACK® 3° Center 22mm x 22mm	4432222	T/L	K031780
VERTE-STACK® 3° Center 22mm x 24mm	4432224	T/L	K031780
VERTE-STACK® 3° Center 22mm x 26mm	4432226	T/L	K031780
VERTE-STACK® 3° Center 22mm x 28mm	4432228	T/L	K031780
VERTE-STACK® 3° Center 22mm x 30mm	4432230	T/L	K031780
VERTE-STACK® 3° Center 22mm x 32mm	4432232	T/L	K031780
VERTE-STACK® 3° Center 22mm x 34mm	4432234	T/L	K031780
VERTE-STACK® 3° Center 22mm x 36mm	4432236	T/L	K031780
VERTE-STACK® 3° Center 22mm x 38mm	4432238	T/L	K031780
VERTE-STACK® 3° Center 22mm x 40mm	4432240	T/L	K031780
VERTE-STACK® 3° Center 22mm x 42mm	4432242	T/L	K031780
VERTE-STACK® 3° Center 22mm x 44mm	4432244	T/L	K031780
VERTE-STACK® 3° Center 22mm x 46mm	4432246	T/L	K031780
VERTE-STACK® 3° Center 22mm x 48mm	4432248	T/L	K031780
VERTE-STACK® 3° Center 22mm x 50mm	4432250	T/L	K031780
VERTE-STACK® 3° Center 22mm x 52mm	4432252	T/L	K031780
VERTE-STACK® 3° Center 26mm x 08mm	4432608	T/L	K031780

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® 3° Center 26mm x 10mm	4432610	T/L	K031780
VERTE-STACK® 3° Center 26mm x 12mm	4432612	T/L	K031780
VERTE-STACK® 3° Center 26mm x 14mm	4432614	T/L	K031780
VERTE-STACK® 3° Center 26mm x 16mm	4432616	T/L	K031780
VERTE-STACK® 3° Center 26mm x 18mm	4432618	T/L	K031780
VERTE-STACK® 3° Center 26mm x 20mm	4432620	T/L	K031780
VERTE-STACK® 3° Center 26mm x 22mm	4432622	T/L	K031780
VERTE-STACK® 3° Center 26mm x 24mm	4432624	T/L	K031780
VERTE-STACK® 3° Center 26mm x 26mm	4432626	T/L	K031780
VERTE-STACK® 3° Center 26mm x 28mm	4432628	T/L	K031780
VERTE-STACK® 3° Center 26mm x 30mm	4432630	T/L	K031780
VERTE-STACK® 3° Center 26mm x 32mm	4432632	T/L	K031780
VERTE-STACK® 3° Center 26mm x 34mm	4432634	T/L	K031780
VERTE-STACK® 3° Center 26mm x 36mm	4432636	T/L	K031780
VERTE-STACK® 3° Center 26mm x 38mm	4432638	T/L	K031780
VERTE-STACK® 3° Center 26mm x 40mm	4432640	T/L	K031780
VERTE-STACK® 3° Center 26mm x 42mm	4432642	T/L	K031780
VERTE-STACK® 3° Center 26mm x 44mm	4432644	T/L	K031780
VERTE-STACK® 3° Center 26mm x 46mm	4432646	T/L	K031780
VERTE-STACK® 3° Center 26mm x 48mm	4432648	T/L	K031780
VERTE-STACK® 3° Center 26mm x 50mm	4432650	T/L	K031780
VERTE-STACK® 3° Center 26mm x 52mm	4432652	T/L	K031780
VERTE-STACK® 6mm X 25	9190625	T/L	K030601
VERTE-STACK® 7mm X 25	9190725	T/L	K030601
VERTE-STACK® 8mm X 25	9190825	T/L	K030601
VERTE-STACK® 6mm X 30	9190630	T/L	K030601
VERTE-STACK® 7mm X 30	9190730	T/L	K030601
VERTE-STACK® 8mm X 30	9190830	T/L	K030601
VERTE-STACK® 6mm X 36	9190636	T/L	K030601
VERTE-STACK® 7mm X 36	9190736	T/L	K030601
VERTE-STACK® 8mm X 36	9190836	T/L	K030601
VERTE-STACK® 9mm X 25	9190925	T/L	K030601
VERTE-STACK® 10mm X 25	9191025	T/L	K030601
VERTE-STACK® 11mm X 25	9191125	T/L	K030601
VERTE-STACK® 12mm X 25	9191225	T/L	K030601
VERTE-STACK® 13mm X 25	9191325	T/L	K030601
VERTE-STACK® 14mm X 25	9191425	T/L	K030601
VERTE-STACK® 15mm X 25	9191525	T/L	K030601
VERTE-STACK® 9mm X 30	9190930	T/L	K030601
VERTE-STACK® 10mm X 30	9191030	T/L	K030601

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® 11mm X 30	9191130	T/L	K030601
VERTE-STACK® 12mm X 30	9191230	T/L	K030601
VERTE-STACK® 13mm X 30	9191330	T/L	K030601
VERTE-STACK® 14mm X 30	9191430	T/L	K030601
VERTE-STACK® 15mm X 30	9191530	T/L	K030601
VERTE-STACK® 16mm X 30	9191630	T/L	K030601
VERTE-STACK® 17mm X 30	9191730	T/L	K030601
VERTE-STACK® 18mm X 30	9191830	T/L	K030601
VERTE-STACK® 9mm X 36	9190936	T/L	K030601
VERTE-STACK® 10mm X 36	9191036	T/L	K030601
VERTE-STACK® 11mm X 36	9191136	T/L	K030601
VERTE-STACK® 12mm X 36	9191236	T/L	K030601
VERTE-STACK® 13mm X 36	9191336	T/L	K030601
VERTE-STACK® 14mm X 36	9191436	T/L	K030601
VERTE-STACK® 15mm X 36	9191536	T/L	K030601
VERTE-STACK® 16mm X 36	9191636	T/L	K030601
VERTE-STACK® 17mm X 36	9191736	T/L	K030601
VERTE-STACK® 18mm X 36	9191836	T/L	K030601
VERTE-STACK® Center, 6mm, 10X25	9192516	T/L	K030601
VERTE-STACK® Center, 7mm, 10X25	9192517	T/L	K030601
VERTE-STACK® Center, 8mm, 10X25	9192518	T/L	K030601
VERTE-STACK® Center, 6mm, 20X25	9192526	T/L	K030601
VERTE-STACK® Center, 7mm, 20X25	9192527	T/L	K030601
VERTE-STACK® Center, 8mm, 20X25	9192528	T/L	K030601
VERTE-STACK® Center, 6mm, 40X25	9192546	T/L	K030601
VERTE-STACK® Center, 7mm, 40X25	9192547	T/L	K030601
VERTE-STACK® Center, 8mm, 40X25	9192548	T/L	K030601
VERTE-STACK® Center, 6mm, 10X30	9193016	T/L	K030601
VERTE-STACK® Center, 7mm, 10X30	9193017	T/L	K030601
VERTE-STACK™ Center, 8mm, 10X30	9193018	T/L	K030601
VERTE-STACK® Center, 6mm, 20X30	9193026	T/L	K030601
VERTE-STACK® Center, 7mm, 20X30	9193027	T/L	K030601
VERTE-STACK® Center, 8mm, 20X30	9193028	T/L	K030601
VERTE-STACK® Center, 6mm, 40X30	9193046	T/L	K030601
VERTE-STACK® Center, 7mm, 40X30	9193047	T/L	K030601
VERTE-STACK® Center, 8mm, 40X30	9193048	T/L	K030601
VERTE-STACK® Center, 6mm, 10X36	9193616	T/L	K030601
VERTE-STACK® Center, 7mm, 10X36	9193617	T/L	K030601
VERTE-STACK® Center, 8mm, 10X36	9193618	T/L	K030601
VERTE-STACK® Center, 6mm, 20X36	9193626	T/L	K030601
VERTE-STACK® Center, 7mm, 20X36	9193627	T/L	K030601

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® Center, 8mm, 20X36	9193628	T/L	K030601
VERTE-STACK® Center, 6mm, 40X36	9193646	T/L	K030601
VERTE-STACK® Center, 7mm, 40X36	9193647	T/L	K030601
VERTE-STACK® Center, 8mm, 40X36	9193648	T/L	K030601
5mm 11x11 Center Piece 0°	8917100	T/L	K030736
5mm 11x11 Center Piece 4°	8917104	T/L	K030736
5mm 11x11 Center Piece 8°	8917108	T/L	K030736
25mm 11x11 Center Piece 0°	8917120	T/L	K030736
25mm 11x11 Center Piece 4°	6276025	T/L	K030736
25mm 11x11 Center Piece 8°	8917128	T/L	K030736
5mm 14x11 Center Piece 0°	8917400	T/L	K030736
5mm 14x11 Center Piece 4°	8917404	T/L	K030736
5mm 14x11 Center Piece 8°	8917408	T/L	K030736
25mm 14x11 Center Piece 0°	8917420	T/L	K030736
25mm 14x11 Center Piece 4°	6277025	T/L	K030736
25mm 14x11 Center Piece 8°	8917428	T/L	K030736
5mm 14x14 Center Piece 0°	8917800	T/L	K030736
5mm 14x14 Center Piece 4°	8917804	T/L	K030736
5mm 14x14 Center Piece 8°	8917808	T/L	K030736
25mm 14x14 Center Piece 0°	8917820	T/L	K030736
25mm 14x14 Center Piece 4°	6278025	T/L	K030736
25mm 14x14 Center Piece 8°	8917828	T/L	K030736
5mm 11x11 End piece	6276511	T/L	K030736
6mm 11x11 End piece	6276611	T/L	K030736
7mm 11x11 End piece	6276711	T/L	K030736
8mm 11x11 End piece	6276811	T/L	K030736
9mm 11x11 End piece	6276911	T/L	K030736
10mm 11x11 End piece	6276011	T/L	K030736
11mm 11x11 End piece	6276111	T/L	K030736
12mm 11x11 End piece	6276211	T/L	K030736
13mm 11x11 End piece	6276311	T/L	K030736
14mm 11x11 End piece	8918114	T/L	K030736
15mm 11x11 End piece	8918115	T/L	K030736
5mm 14x11 End piece	6277541	T/L	K030736
6mm 14x11 End piece	6277641	T/L	K030736
7mm 14x11 End piece	6277741	T/L	K030736
8mm 14x11 End piece	6277841	T/L	K030736
9mm 14x11 End piece	6277941	T/L	K030736
10mm 14x11 End piece	6277041	T/L	K030736
11mm 14x11 End piece	6277141	T/L	K030736
12mm 14x11 End piece	6277241	T/L	K030736
13mm 14x11 End piece	6277341	T/L	K030736
14mm 14x11 End piece	8918414	T/L	K030736
15mm 14x11 End piece	8918415	T/L	K030736
5mm 14x14 End piece	6278544	T/L	K030736

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VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
6mm 14x14 End piece	6278644	T/L	K030736
7mm 14x14 End piece	6278744	T/L	K030736
8mm 14x14 End piece	6278844	T/L	K030736
9mm 14x14 End piece	6278944	T/L	K030736
10mm 14x14 End piece	6278044	T/L	K030736
11mm 14x14 End piece	6278144	T/L	K030736
12mm 14x14 End piece	6278244	T/L	K030736
13mm 14x14 End piece	6278344	T/L	K030736
14mm 14x14 End piece	8918814	T/L	K030736
15mm 14x14 End piece	8918815	T/L	K030736
12mm Add-on Cage, Flat, Small	8915012	T/L	K021791
14mm Add-on Cage, Flat, Small	8915014	T/L	K021791
16mm Add-on Cage, Flat, Small	8915016	T/L	K021791
18mm Add-on Cage, Flat, Small	8915018	T/L	K021791
20mm Add-on Cage, Flat, Small	8915020	T/L	K021791
12mm Add-on Cage, Lordotic, Small	8915412	T/L	K021791
14mm Add-on Cage, Lordotic, Small	8915414	T/L	K021791
16mm Add-on Cage, Lordotic, Small	8915416	T/L	K021791
18mm Add-on Cage, Lordotic, Small	8915418	T/L	K021791
20mm Add-on Cage, Lordotic, Small	8915420	T/L	K021791
5mm Center Cage, Small	8915805	T/L	K021791
10mm Center Cage, Small	8915810	T/L	K021791
20mm Center Cage, Small	8915820	T/L	K021791
30mm Center Cage, Small	8915830	T/L	K021791
40mm Center Cage, Small	8915840	T/L	K021791
12mm Add-on Cage, Flat, Medium	8919012	T/L	K021791
14mm Add-on Cage, Flat, Medium	8919014	T/L	K021791
16mm Add-on Cage, Flat, Medium	8919016	T/L	K021791
18mm Add-on Cage, Flat, Medium	8919018	T/L	K021791
20mm Add-on Cage, Flat, Medium	8919020	T/L	K021791
12mm Add-on Cage, Lordotic, Medium	8919412	T/L	K021791
14mm Add-on Cage, Lordotic, Medium	8919414	T/L	K021791
16mm Add-on Cage, Lordotic, Medium	8919416	T/L	K021791
18mm Add-on Cage, Lordotic, Medium	8919418	T/L	K021791
20mm Add-on Cage, Lordotic, Medium	8919420	T/L	K021791
5mm Center Cage, Medium	8919805	T/L	K021791
10mm Center Cage, Medium	8919810	T/L	K021791
20mm Center Cage, Medium	8919820	T/L	K021791
30mm Center Cage, Medium	8919830	T/L	K021791
40mm Center Cage, Medium	8919840	T/L	K021791
12mm Add-on Cage, Flat, Large	8916012	T/L	K021791
14mm Add-on Cage, Flat, Large	8916014	T/L	K021791
16mm Add-on Cage, Flat, Large	8916016	T/L	K021791
18mm Add-on Cage, Flat, Large	8916018	T/L	K021791
20mm Add-on Cage, Flat, Large	8916020	T/L	K021791
12mm Add-on Cage, Lordotic, Large	8916412	T/L	K021791

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
14mm Add-on Cage, Lordotic, Large	8916414	T/L	K021791
16mm Add-on Cage, Lordotic, Large	8916416	T/L	K021791
18mm Add-on Cage, Lordotic, Large	8916418	T/L	K021791
20mm Add-on Cage, Lordotic, Large	8916420	T/L	K021791
5mm Center Cage, Large	8916805	T/L	K021791
10mm Center Cage, Large	8916810	T/L	K021791
20mm Center Cage, Large	8916820	T/L	K021791
30mm Center Cage, Large	8916830	T/L	K021791
40mm Center Cage, Large	8916840	T/L	K021791
8mm Add-On, Flat Small	8915008	T/L	K030735
10mm Add-On, Flat Small	8915010	T/L	K030735
8mm Add-On, Lordotic 8° Small	8915408	T/L	K030735
10mm Add-On, Lordotic 8° Small	8915410	T/L	K030735
8mm Add-On, Flat Small Convex	8915108	T/L	K030735
10mm Add-On, Flat Small Convex	8915110	T/L	K030735
12mm Add-On, Flat Small Convex	8915112	T/L	K030735
14mm Add-On, Flat Small Convex	8915114	T/L	K030735
16mm Add-On, Flat Small Convex	8915116	T/L	K030735
18mm Add-On, Flat Small Convex	8915118	T/L	K030735
20mm Add-On, Flat Small Convex	8915120	T/L	K030735
8mm Add-On, Lordotic 8° Small Convex	8915508	T/L	K030735
10mm Add-On, Lordotic 8° Small Convex	8915510	T/L	K030735
12mm Add-On, Lordotic 8° Small Convex	8915512	T/L	K030735
14mm Add-On, Lordotic 8° Small Convex	8915514	T/L	K030735
16mm Add-On, Lordotic 8° Small Convex	8915516	T/L	K030735
18mm Add-On, Lordotic 8° Small Convex	8915518	T/L	K030735
20mm Add-On, Lordotic 8° Small Convex	8915520	T/L	K030735
5mm Center Piece Small Convex	8915705	T/L	K030735
™ 10mm Center Piece Small Convex	8915710	T/L	K030735
20mm Center Piece Small Convex	8915720	T/L	K030735
30mm Center Piece Small Convex	8915730	T/L	K030735
40mm Center Piece Small Convex	8915740	T/L	K030735
8mm Add-On, Flat Large	8916008	T/L	K030735
10mm Add-On, Flat Large	8916010	T/L	K030735
8mm Add-On, Lordotic 8° Large	8916408	T/L	K030735
10mm Add-On, Lordotic 8° Large	8916410	T/L	K030735
8mm Add-On, Flat Large Convex	8916108	T/L	K030735
10mm Add-On, Flat Large Convex	8916110	T/L	K030735
12mm Add-On, Flat Large Convex	8916112	T/L	K030735
14mm Add-On, Flat Large Convex	8916114	T/L	K030735
16mm Add-On, Flat Large Convex	8916116	T/L	K030735
18mm Add-On, Flat Large Convex	8916118	T/L	K030735
20mm Add-On, Flat Large Convex	8916120	T/L	K030735
8mm Add-On, Lordotic 8° Large Convex	8916508	T/L	K030735
10mm Add-On, Lordotic 8° Large Convex	8916510	T/L	K030735

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
12mm Add-On, Lordotic 8° Large Convex	8916512	T/L	K030735
14mm Add-On, Lordotic 8° Large Convex	8916514	T/L	K030735
16mm Add-On, Lordotic 8° Large Convex	8916516	T/L	K030735
18mm Add-On, Lordotic 8° Large Convex	8916518	T/L	K030735
20mm Add-On, Lordotic 8° Large Convex	8916520	T/L	K030735
5mm Center Piece Large Convex	8916705	T/L	K030735
10mm Center Piece Large Convex	8916710	T/L	K030735
20mm Center Piece Large Convex	8916720	T/L	K030735
30mm Center Piece Large Convex	8916730	T/L	K030735
40mm Center Piece Large Convex	8916740	T/L	K030735
8mm Add-On, Flat Medium	8919008	T/L	K030735
10mm Add-On, Flat Medium	8919010	T/L	K030735
8mm Add-On, Lordotic 8° Medium	8919408	T/L	K030735
10mm Add-On, Lordotic 8° Medium	8919410	T/L	K030735
8mm Add-On, Flat Medium Convex	8919108	T/L	K030735
10mm Add-On, Flat Medium Convex	8919110	T/L	K030735
12mm Add-On, Flat Medium Convex	8919112	T/L	K030735
14mm Add-On, Flat Medium, Convex	8919114	T/L	K030735
16mm Add-On, Flat Medium, Convex	8919116	T/L	K030735
18mm Add-On, Flat Medium Convex	8919118	T/L	K030735
20mm Add-On, Flat Medium, Convex	8919120	T/L	K030735
8mm Add-On, Lordotic 8° Medium Convex	8919508	T/L	K030735
10mm Add-On, Lordotic 8° Medium Convex	8919510	T/L	K030735
12mm Add-On, Lordotic 8° Medium Convex	8919512	T/L	K030735
14mm Add-On, Lordotic 8° Medium Convex	8919514	T/L	K030735
16mm Add-On, Lordotic 8° Medium Convex	8919516	T/L	K030735
18mm Add-On, Lordotic 8° Medium Convex	8919518	T/L	K030735
20mm Add-On, Lordotic 8° Medium Convex	8919520	T/L	K030735
5mm Center Piece Medium Convex	8919705	T/L	K030735
V10mm Center Piece Medium Convex	8919710	T/L	K030735
20mm Center Piece Medium Convex	8919720	T/L	K030735
30mm Center Piece Medium Convex	8919730	T/L	K030735
40mm Center Piece Medium Convex	8919740	T/L	K030735
Titanium VERTE-STACK® 6mm X 25	9196506	T/L	K040167
Titanium VERTE-STACK® 7mm X 25	9196507	T/L	K040167
Titanium VERTE-STACK® 8mm X 25	9196508	T/L	K040167
Titanium VERTE-STACK® 9mm X 25	9196509	T/L	K040167
Titanium VERTE-STACK® 10mm X 25	9196510	T/L	K040167
Titanium VERTE-STACK® 11mm X 25	9196511	T/L	K040167
Titanium VERTE-STACK® 12mm X 25	9196512	T/L	K040167
Titanium VERTE-STACK® 13mm X 25	9196513	T/L	K040167
Titanium VERTE-STACK® 14mm X 25	9196514	T/L	K040167
Titanium VERTE-STACK® 15mm X 25	9196515	T/L	K040167
Titanium VERTE-STACK® 7mm X 30	9196007	T/L	K040167

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
Titanium VERTE-STACK® 8mm X 30	9196008	T/L	K040167
Titanium VERTE-STACK® 9mm X 30	9196009	T/L	K040167
Titanium VERTE-STACK® 10mm X 30	9196010	T/L	K040167
Titanium VERTE-STACK® 11mm X 30	9196011	T/L	K040167
Titanium VERTE-STACK® 12mm X 30	9196012	T/L	K040167
Titanium VERTE-STACK® 13mm X 30	9196013	T/L	K040167
Titanium VERTE-STACK® 14mm X 30	9196014	T/L	K040167
Titanium VERTE-STACK® 15mm X 30	9196015	T/L	K040167
Titanium VERTE-STACK® 16mm X 30	9196016	T/L	K040167
Titanium VERTE-STACK® 17mm X 30	9196017	T/L	K040167
Titanium VERTE-STACK® 18mm X 30	9196018	T/L	K040167
Titanium VERTE-STACK® 7mm X 36	9196607	T/L	K040167
Titanium VERTE-STACK® 8mm X 36	9196608	T/L	K040167
Titanium VERTE-STACK® 9mm X 36	9196609	T/L	K040167
Titanium VERTE-STACK® 10mm X 36	9196610	T/L	K040167
Titanium VERTE-STACK® 11mm X 36	9196611	T/L	K040167
Titanium VERTE-STACK® 12mm X 36	9196612	T/L	K040167
Titanium VERTE-STACK® 13mm X 36	9196613	T/L	K040167
Titanium VERTE-STACK® 14mm X 36	9196614	T/L	K040167
Titanium VERTE-STACK® 15mm X 36	9196615	T/L	K040167
Titanium VERTE-STACK® 16mm X 36	9196616	T/L	K040167
Titanium VERTE-STACK® 17mm X 36	9196617	T/L	K040167
Titanium VERTE-STACK® 18mm X 36	9196618	T/L	K040167
Titanium VERTE-STACK® Center, 6mm, 25X10	9197101	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 25X10	9197102	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 25X10	9197103	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 25X10	9197104	T/L	K040167
Titanium VERTE-STACK® Center, 10mm, 25X10	9197105	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 25X10	9197106	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 25X10	9197107	T/L	K040167
Titanium VERTE-STACK® Center, 13mm, 25X10	9197108	T/L	K040167
Titanium VERTE-STACK® Center, 14mm, 25X10	9197109	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 25X10	9197110	T/L	K040167
Titanium VERTE-STACK® Center, 6mm, 25X20	9197111	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 25X20	9197112	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 25X20	9197113	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 25X20	9197114	T/L	K040167
Titanium VERTE-STACK® Center, 10mm, 25X20	9197115	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 25X20	9197116	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 25X20	9197117	T/L	K040167

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
Titanium VERTE-STACK® Center, 13mm, 25X20	9197118	T/L	K040167
Titanium VERTE-STACK® Center, 14mm, 25X20	9197119	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 25X20	9197120	T/L	K040167
Titanium VERTE-STACK® Center, 6mm, 25X40	9197121	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 25X40	9197122	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 25X40	9197123	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 25X40	9197124	T/L	K040167
Titanium VERTE-STACK® Center, 10mm, 25X40	9197125	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 25X40	9197126	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 25X40	9197127	T/L	K040167
Titanium VERTE-STACK® Center, 13mm, 25X40	9197128	T/L	K040167
Titanium VERTE-STACK® Center, 14mm, 25X40	9197129	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 25X40	9197130	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 30X10	9197201	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 30X10	9197202	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 30X10	9197203	T/L	K040167
Titanium VERTE-STACK® Center, 10mm, 30X10	9197204	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 30X10	9197205	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 30X10	9197206	T/L	K040167
Titanium VERTE-STACK® Center, 13mm, 30X10	9197207	T/L	K040167
Titanium VERTE-STACK® Center, 14mm, 30X10	9197208	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 30X10	9197209	T/L	K040167
Titanium VERTE-STACK® Center, 16mm, 30X10	9197210	T/L	K040167
Titanium VERTE-STACK® Center, 17mm, 30X10	9197211	T/L	K040167
Titanium VERTE-STACK® Center, 18mm, 30X10	9197212	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 30X20	9197213	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 30X20	9197214	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 30X20	9197215	T/L	K040167
Titanium VERTE-STACK® Center, 10mm, 30X20	9197216	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 30X20	9197217	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 30X20	9197218	T/L	K040167
Titanium VERTE-STACK® Center, 13mm, 30X20	9197219	T/L	K040167
Titanium VERTE-STACK® Center, 14mm, 30X20	9197220	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 30X20	9197221	T/L	K040167
Titanium VERTE-STACK® Center, 16mm, 30X20	9197222	T/L	K040167
Titanium VERTE-STACK® Center, 17mm, 30X20	9197223	T/L	K040167
Titanium VERTE-STACK® Center, 18mm, 30X20	9197224	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 30X40	9197225	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 30X40	9197226	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 30X40	9197227	T/L	K040167

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
Titanium VERTE-STACK® Center, 10mm, 30X40	9197228	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 30X40	9197229	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 30X40	9197230	T/L	K040167
Titanium VERTE-STACK® Center, 13mm, 30X40	9197231	T/L	K040167
Titanium VERTE-STACK® Center, 14mm, 30X40	9197232	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 30X40	9197233	T/L	K040167
Titanium VERTE-STACK® Center, 16mm, 30X40	9197234	T/L	K040167
Titanium VERTE-STACK® Center, 17mm, 30X40	9197235	T/L	K040167
Titanium VERTE-STACK® Center, 18mm, 30X40	9197236	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 36X10	9197301	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 36X10	9197302	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 36X10	9197303	T/L	K040167
Titanium VERTE-STACK® Center, 10mm, 36X10	9197304	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 36X10	9197305	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 36X10	9197306	T/L	K040167
Titanium VERTE-STACK® Center, 13mm, 36X10	9197307	T/L	K040167
Titanium VERTE-STACK® Center, 14mm, 36X10	9197308	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 36X10	9197309	T/L	K040167
Titanium VERTE-STACK® Center, 16mm, 36X10	9197310	T/L	K040167
Titanium VERTE-STACK® Center, 17mm, 36X10	9197311	T/L	K040167
Titanium VERTE-STACK® Center, 18mm, 36X10	9197312	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 36X20	9197313	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 36X20	9197314	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 36X20	9197315	T/L	K040167
Titanium VERTE-STACK® Center, 10mm, 36X20	9197316	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 36X20	9197317	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 36X20	9197318	T/L	K040167
Titanium VERTE-STACK® Center, 13mm, 36X20	9197319	T/L	K040167
Titanium VERTE-STACK® Center, 14mm, 36X20	9197320	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 36X20	9197321	T/L	K040167
Titanium VERTE-STACK® Center, 16mm, 36X20	9197322	T/L	K040167
Titanium VERTE-STACK® Center, 17mm, 36X20	9197323	T/L	K040167
Titanium VERTE-STACK® Center, 18mm, 36X20	9197324	T/L	K040167
Titanium VERTE-STACK® Center, 7mm, 36X40	9197325	T/L	K040167
Titanium VERTE-STACK® Center, 8mm, 36X40	9197326	T/L	K040167
Titanium VERTE-STACK® Center, 9mm, 36X40	9197327	T/L	K040167
Titanium VERTE-STACK® Center, 10mm, 36X40	9197328	T/L	K040167
Titanium VERTE-STACK® Center, 11mm, 36X40	9197329	T/L	K040167
Titanium VERTE-STACK® Center, 12mm, 36X40	9197330	T/L	K040167
Titanium VERTE-STACK® Center, 13mm, 36X40	9197331	T/L	K040167

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
Titanium VERTE-STACK® Center, 14mm, 36X40	9197332	T/L	K040167
Titanium VERTE-STACK® Center, 15mm, 36X40	9197333	T/L	K040167
Titanium VERTE-STACK® Center, 16mm, 36X40	9197334	T/L	K040167
Titanium VERTE-STACK® Center, 17mm, 36X40	9197335	T/L	K040167
Titanium VERTE-STACK® Center, 18mm, 36X40	9197336	T/L	K040167
Titanium VERTE-STACK® 3mm Lock Screw	9196000	T/L	K040167
VERTE-STACK® PERIMETER Small Add-On 4° 8mm	3291208	T/L	K041452
VERTE-STACK® PERIMETER Small Add-On 4° 10mm	3291210	T/L	K041452
VERTE-STACK® PERIMETER Small Add-On 4° 12mm	3291212	T/L	K041452
VERTE-STACK® PERIMETER Small Add-On 4° 14mm	3291214	T/L	K041452
VERTE-STACK® PERIMETER Small Add-On 4° 16mm	3291216	T/L	K041452
VERTE-STACK® PERIMETER Small Add-On 4° 18mm	3291218	T/L	K041452
VERTE-STACK® PERIMETER Small Add-On 4° 20mm	3291220	T/L	K041452
VERTE-STACK® PERIMETER Medium Add-On 8° 8mm	3292308	T/L	K041452
VERTE-STACK® PERIMETER Medium Add-On 8° 10mm	3292310	T/L	K041452
VERTE-STACK® PERIMETER Medium Add-On 8° 12mm	3292312	T/L	K041452
VERTE-STACK® PERIMETER Medium Add-On 8° 14mm	3292314	T/L	K041452
VERTE-STACK® PERIMETER Medium Add-On 8° 16mm	3292316	T/L	K041452
VERTE-STACK® PERIMETER Medium Add-On 8° 18mm	3292318	T/L	K041452
VERTE-STACK® PERIMETER Medium Add-On 8° 20mm	3292320	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 8° 8mm	3293308	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 8° 10mm	3293310	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 8° 12mm	3293312	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 8° 14mm	3293314	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 8° 16mm	3293316	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 8° 18mm	3293318	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 8° 20mm	3293320	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 12° 12mm	3293412	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 12° 14mm	3293414	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 12° 16mm	3293416	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 12° 18mm	3293418	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 12° 20mm	3293420	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 15° 12mm	3293512	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 15° 14mm	3293514	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 15° 16mm	3293516	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 15° 18mm	3293518	T/L	K041452
VERTE-STACK® PERIMETER Large Add-On 15° 20mm	3293520	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 22mm	3294222	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 26mm	3294226	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 30mm	3294230	T/L	K041452

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® PERIMETER Small Center Piece 4° 34mm	3294234	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 38mm	3294238	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 42mm	3294242	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 46mm	3294246	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 48mm	3294248	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 52mm	3294252	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 56mm	3294256	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 60mm	3294260	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 62mm	3294262	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 66mm	3294266	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 70mm	3294270	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 72mm	3294272	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 76mm	3294276	T/L	K041452
VERTE-STACK® PERIMETER Small Center Piece 4° 80mm	3294280	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 22mm	3295322	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 26mm	3295326	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 30mm	3295330	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 34mm	3295334	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 38mm	3295338	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 42mm	3295342	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 46mm	3295346	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 48mm	3295348	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 52mm	3295352	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 56mm	3295356	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 60mm	3295360	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 62mm	3295362	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 66mm	3295366	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 70mm	3295370	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 72mm	3295372	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 76mm	3295376	T/L	K041452
VERTE-STACK® PERIMETER Medium Center Piece 8° 80mm	3295380	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 22mm	3296322	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 26mm	3296326	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 30mm	3296330	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 34mm	3296334	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 38mm	3296338	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 42mm	3296342	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 46mm	3296346	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 48mm	3296348	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 52mm	3296352	T/L	K041452

VERTE-STACK® Spinal System Implant Table
(Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® PERIMETER Large Center Piece 8° 56mm	3296356	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 60mm	3296360	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 62mm	3296362	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 66mm	3296366	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 70mm	3296370	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 72mm	3296372	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 76mm	3296376	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 8° 80mm	3296380	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 22mm	3296422	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 26mm	3296426	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 30mm	3296430	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 34mm	3296434	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 38mm	3296438	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 42mm	3296442	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 46mm	3296446	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 48mm	3296448	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 52mm	3296452	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 56mm	3296456	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 60mm	3296460	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 62mm	3296462	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 66mm	3296466	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 70mm	3296470	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 72mm	3296472	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 76mm	3296476	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 12° 80mm	3296480	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 22mm	3296522	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 26mm	3296526	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 30mm	3296530	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 34mm	3296534	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 38mm	3296538	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 42mm	3296542	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 46mm	3296546	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 48mm	3296548	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 52mm	3296552	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 56mm	3296556	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 60mm	3296560	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 62mm	3296562	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 66mm	3296566	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 70mm	3296570	T/L	K041452
VERTE-STACK® PERIMETER Large Center Piece 15° 72mm	3296572	T/L	K041452

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK® PERIMETER Large Center Piece 15° 76mm	3296576	T/L	K041452
VERTE-STACK™ PERIMETER Large Center Piece 15° 80mm	3296580	T/L	K041452
VERTE-STACK™ PERIMETER Small Add-On 4° 8mm	3391208	T/L	K043566
VERTE-STACK™ PERIMETER Small Add-On 4° 10mm	3391210	T/L	K043566
VERTE-STACK™ PERIMETER Small Add-On 4° 12mm	3391212	T/L	K043566
VERTE-STACK™ PERIMETER Small Add-On 4° 14mm	3391214	T/L	K043566
VERTE-STACK™ PERIMETER Small Add-On 4° 16mm	3391216	T/L	K043566
VERTE-STACK™ PERIMETER Small Add-On 4° 18mm	3391218	T/L	K043566
VERTE-STACK™ PERIMETER Small Add-On 4° 20mm	3391220	T/L	K043566
VERTE-STACK™ PERIMETER Medium Add-On 8° 8mm	3392308	T/L	K043566
VERTE-STACK™ PERIMETER Medium Add-On 8° 10mm	3392310	T/L	K043566
VERTE-STACK™ PERIMETER Medium Add-On 8° 12mm	3392312	T/L	K043566
VERTE-STACK™ PERIMETER Medium Add-On 8° 14mm	3392314	T/L	K043566
VERTE-STACK™ PERIMETER Medium Add-On 8° 16mm	3392316	T/L	K043566
VERTE-STACK™ PERIMETER Medium Add-On 8° 18mm	3392318	T/L	K043566
VERTE-STACK™ PERIMETER Medium Add-On 8° 20mm	3392320	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 8° 8mm	3393308	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 8° 10mm	3393310	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 8° 12mm	3393312	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 8° 14mm	3393314	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 8° 16mm	3393316	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 8° 18mm	3393318	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 8° 20mm	3393320	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 12° 12mm	3393412	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 12° 14mm	3393414	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 12° 16mm	3393416	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 12° 18mm	3393418	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 12° 20mm	3393420	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 15° 12mm	3393512	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 15° 14mm	3393514	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 15° 16mm	3393516	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 15° 18mm	3393518	T/L	K043566
VERTE-STACK™ PERIMETER Large Add-On 15° 20mm	3393520	T/L	K043566
VERTE-STACK™ PERIMETER Extra Large Add-On 8° 8mm	3394308	T/L	K043566
VERTE-STACK™ PERIMETER Extra Large Add-On 8° 10mm	3394310	T/L	K043566
VERTE-STACK™ PERIMETER Extra Large Add-On 8° 12mm	3394312	T/L	K043566
VERTE-STACK™ PERIMETER Extra Large Add-On 8° 14mm	3394314	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 22mm	3394222	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 26mm	3394226	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 30mm	3394230	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 34mm	3394234	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 38mm	3394238	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 42mm	3394242	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 46mm	3394246	T/L	K043566

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK™ PERIMETER Small Center Piece 4° 48mm	3394248	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 52mm	3394252	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 56mm	3394256	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 60mm	3394260	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 62mm	3394262	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 66mm	3394266	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 70mm	3394270	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 72mm	3394272	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 76mm	3394276	T/L	K043566
VERTE-STACK™ PERIMETER Small Center Piece 4° 80mm	3394280	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 22mm	3395322	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 26mm	3395326	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 30mm	3395330	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 34mm	3395334	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 38mm	3395338	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 42mm	3395342	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 46mm	3395346	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 48mm	3395348	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 52mm	3395352	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 56mm	3395356	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 60mm	3395360	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 62mm	3395362	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 66mm	3395366	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 70mm	3395370	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 72mm	3395372	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 76mm	3395376	T/L	K043566
VERTE-STACK™ PERIMETER Medium Center Piece 8° 80mm	3395380	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 22mm	3396322	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 26mm	3396326	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 30mm	3396330	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 34mm	3396334	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 38mm	3396338	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 42mm	3396342	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 46mm	3396346	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 48mm	3396348	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 52mm	3396352	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 56mm	3396356	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 60mm	3396360	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 62mm	3396362	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 66mm	3396366	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 70mm	3396370	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 72mm	3396372	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 76mm	3396376	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 8° 80mm	3396380	T/L	K043566

VERTE-STACK® Spinal System Implant Table (Continued)

VERTE-STACK® IMPLANTS[1]	REFERENCE NUMBER	SPINAL LEVELS	510(k) REF. NO.
VERTE-STACK™ PERIMETER Large Center Piece 12° 22mm	3396422	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 26mm	3396426	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 30mm	3396430	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 34mm	3396434	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 38mm	3396438	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 42mm	3396442	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 46mm	3396446	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 48mm	3396448	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 52mm	3396452	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 56mm	3396456	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 60mm	3396460	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 62mm	3396462	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 66mm	3396466	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 70mm	3396470	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 72mm	3396472	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 76mm	3396476	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 12° 80mm	3396480	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 22mm	3396522	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 26mm	3396526	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 30mm	3396530	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 34mm	3396534	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 38mm	3396538	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 42mm	3396542	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 46mm	3396546	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 48mm	3396548	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 52mm	3396552	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 56mm	3396556	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 60mm	3396560	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 62mm	3396562	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 66mm	3396566	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 70mm	3396570	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 72mm	3396572	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 76mm	3396576	T/L	K043566
VERTE-STACK™ PERIMETER Large Center Piece 15° 80mm	3396580	T/L	K043566

Note: The currently used trade name for each of the previously cleared components is given in the table. However, for marketing or other reasons, Medtronic Sofamor Danek reserves the right to change the trade name of any or all of the listed components. All other company labeling would be appropriately modified.

Instruments and Sterilization Trays

Used with the VERTE-STACK™ Spinal System

VERTE-STACK® Spinal System Implant Table (Continued)

INSTRUMENTS	REFERENCE NUMBER
Caliper	8910675
Small Inserter	8917000
Small Trial	8917005
Large Trial	8917006
Large Inserter	8917010
Spreader	8917050
VERTE-STACK® Kit	8919950
Implant Inserter	9192000
Adjuster	9192004
VERTE-STACK® Suitcase Tray	8919951
VERTE-STACK® Sterilization Tray	8919952
VERTE-STACK® Lid	8919953
Threaded Inserter	6279001
End Cap Threaded Inserter	6279002
Caliper	6279004
Micro-Endo Ruler	950-146
Mallet	875-716
PSR Loading Block	6279005
PSR Instrument Case	6279009
PSR Lid for Instrument Case	6279010

Attachment 6

Engineering Drawings

(b)(4) Pages 130-134 Schematics

[redacted]

CONFIDENTIAL

Attachment 7

Indications of Use Statement

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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 Sofamor Danek ZPLATE II Anterior Fixation System, DYNALOK® CLASSIC Spinal System, the VANTAGE® Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, the GDLH® Spinal System, or their successors. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

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

_____ _____ _____ _____

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional 1-2-96)

000100

(b)(4) pages 137-149 Testing