Centinel Spine K142079

FDA CDRH DMC
JUL 31 2014
Received

July 30, 2014

Office of Device Evaluation
U.S. Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Application – Modified Indications for Use
Centinel Spine, Inc. STALIF C®

Dear Sir or Madam:

In accordance with 21 CFR 807, Section E, Centinel Spine, Inc. is submitting this Traditional Premarket Notification for minor design modifications to STALIF C®. The STALIF C® was cleared by the FDA in K133200, K120819, and K072415.

We are providing an electronic copy (eCopy) of this 510(k) per FDA's web instructions, and it is an exact duplicate of the paper copy.

The completed "Refuse to Accept" checklist is provided in **Attachment A**. The device does not include software or require EMC and Electrical Safety evaluation. The device is not an in vitro diagnostic device.

The purpose of this Traditional 510(k) is to extend the STALIF C® (K133200, K120819, K072415) indications for use by expanding the available grafting options to include allogenic bone graft in addition to the already cleared autogenous bone graft option. The changes (detailed in sections 3 and 6) modify the indications for use of the STALIF C® Intervertebral Body Fusion Device, but do not alter the fundamental scientific technology of these devices.

The contact for communications regarding this 510(k) submission is:

Mr. John Parry
Development Manager
Centinel Spine, Inc.
900 Airport Road, Suite 3B
West Chester, PA 19380
Phone: 484.887.8813
Fax: 800.493.0966

J.Parry@centinelspine.com

A secondary contact for this 510(k) submission is:

Mr. Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Office: 202.552.5804
Fax: 202.552.5798
jeggleton@mcra.com

Centinel Spine, Inc. considers all material provided herein as Privileged and Confidential and we request that the FDA handle this information as such per the provisions detailed in 21 CFR 20.61.

Notice of the FDA decision regarding this Premarket Notification should be faxed to the attention of Mr. John Parry at 800.493.0966. Please forward an electronic copy of the letter to J.Parry@centinelspine.com

We appreciate FDA's earliest attention to this 510(k) submission.

Kind regards,

Mr. John Parry
Development Manager
Centinel Spine, Inc.

Centinel Spine

July 30, 2014

Office of Device Evaluation
U.S. Food and Drug Administration
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Kind regards,

Mr. John Parry
Development Manager
Centinel Spine, Inc.

Traditional
Pre-Market Notification 510(k)

STALIF C® and STALIF C® Ti
Intervertebral Body Fusion Device

Official Contact:

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Confidential

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret Process, Product Specs Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov /oc/mdufma/coversheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) CENTINEL SPINE INC 900 Airport Road Suite 3B West Chester PA 19380 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4) Trade Secret Process	2. CONTACT NAME Lisa Buckley 2.1 E-MAIL ADDRESS l.buckley@centinelspine.com 2.2 TELEPHONE NUMBER (include Area code) 484-887-8803 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments /ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. 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

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 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

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) Trade S t P [redacted] 09-Apr-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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)*
07/30/2014	(b)(4) Trade Secret Process	N/A

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: Centinel Spine, Inc.	Establishment Registration Number *(if known)*: 3007494564		
Division Name *(if applicable)*:	Phone Number *(including area code)*: (484) 887-8813		
Street Address: 900 Airport Road, Suite 3B	FAX Number *(including area code)*: (800) 493-0966		
City: West Chester	State / Province: PA	ZIP/Postal Code: 19380	Country: USA
Contact Name: Mr. John Parry			
Contact Title: Development Manager	Contact E-mail Address: j.parry@centinelspine.com		

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

Company / Institution Name: MCRA, LLC			
Division Name *(if applicable)*:	Phone Number *(including area code)*: (202) 552-5800		
Street Address: 1331 H Street NW, 12th Floor	FAX Number *(including area code)*: (202) 552-5798		
City: Washington	State / Province: DC	ZIP/Postal Code: 20005	Country: USA
Contact Name: Justin Eggleton			
Contact Title: Director, Spine Regulatory Affairs	Contact E-mail Address: jeggleton@mcra.com		

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)

- ☐ New Device
- ☑ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OVE	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 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	K133200	1	STALIF C Ti	1	Centinel Spine, Inc.
2	K120189	2	STALIF C	2	Centinel Spine, Inc.
3	K130177	3	Anatomic PEEK Cervical Fusion System	3	Medtronic
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

21 CFR 888.3080; Intervertebral body fixation orthosis

	Trade or Proprietary or Model Name for This Device		Model Number
1	STALIF C Ti	1	see device description
2	STALIF C	2	see device description
3		3	
4		4	
5		5	

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

1 None	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OVE	21 CFR 888.3080	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Orthopedic

Indications *(from labeling)*

The STALIF C® and STALIF C® Ti devices are intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion. STALIF C® and STALIF C® Ti are intended to be used at one level.

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	☐ 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	

☐ 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			See Attachment K.		
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

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1. Administrative Information

1.1 *Manufacturer*

Centinel Spine, Inc.
900 Airport Road, Suite 3B
West Chester, PA 19380
Phone: 484.887.8810

1.2 *Submission Correspondents*

Primary Contact
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Centinel Spine, Inc.
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Secondary Contact
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Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: 202.552.5800
Fax: 202.552.5798
Email: jeggleton@mcra.com

1.3 *Device Information*

Trade Name: STALIF C® and STALIF C® Ti

Device Type: Intervertebral Fusion Device with Bone Graft, Cervical

1.4 *Device Classification*

Class: II

Classifications:

- 21 CFR §888.3080, Intervertebral Fusion Device

Product Codes:

- OVE

2. Device Description

The purpose of this Traditional 510(k) is to modify the STALIF C® (K133200, K120819, K072415) indications for use to expand the available grafting options to include the option of using allogenic bone graft as an adjunct to the device to facilitate the fusion process. The device design is identical to the STALIF C® cleared in K133200 and K120819. Please refer to K133200 and K120819 for a more comprehensive device description and engineering drawings. For ease of review, a device description has been replicated in Section 2.1.

This modification to the indications for use is in response to postmarketing surveillance activities, industry trends, scientific literature, and recent FDA 510(k) clearances. Furthermore, it is intended to provide the operating surgeon with additional options when selecting a fusion material for anterior cervical discectomy and fusion procedures. These changes are not due to adverse events or issues with the device or implantation. The STALIF C® and STALIF C® Ti indications for use have been modified, but the device has not been modified in any way. The fundamental scientific technology of the device has also not been altered. Centinel Spine, Inc. will continue to market the predicate STALIF C® and STALIF C® Ti devices.

Please refer to K133200 and K120819 for a complete STALIF C® and STALIF C® Ti engineering drawings. They are also provided in **Attachment B** for convenience.

Specifically, this Traditional 510(k) is being submitted to:

- Expand the STALIF C® and STALIF C® Ti indications for use to include the option of using allogenic bone graft as an adjunct to the device to facilitate fusion. This use is in addition to the previously cleared option of using autogenic bone graft.

There are no other modifications to the device or labeling in this 510(k).

2.1 STALIF C®

2.1.1 Three Screw Cages

Figure 1 shows the 11.5mm three screw device.

(b)(4) Trade Secret Process - Design

[redacted]

(b)(4) Trade Secret Process - Design

[redacted]

2.2 STALIF C® Ti

The STALIF C® Ti device has an identical design to the device cleared in K133200. The following description was provided in that 510(k) and is provided here for matters of convenience. The biocompatible CP Ti coating (ASTM F1580) is applied to the device surfaces that contact the bony endplates (Figure 4). The device is available in a variety of depths (AP profile), heights and profiles. (b)(4) Trade Secret Process - Product Specs [redacted]

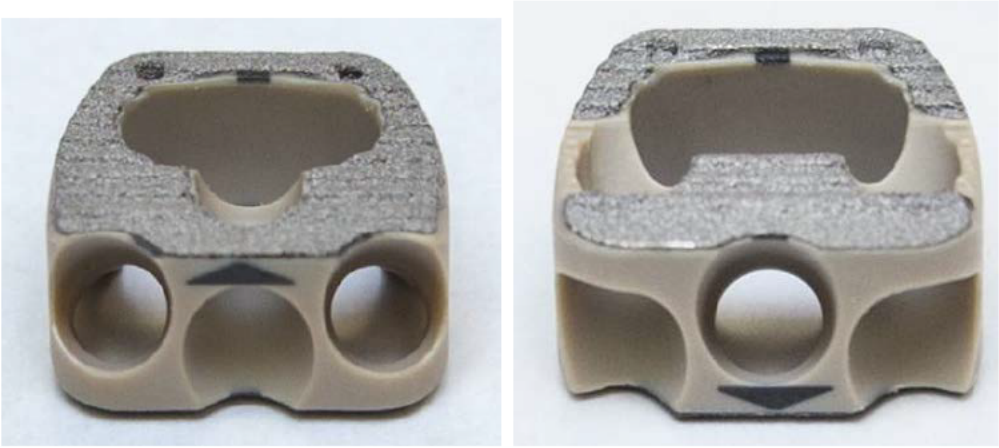

Figure 4: Images of modified STALIF C® device with CPTi plasma-spray coating shown on superior (left) and inferior (right) surfaces

(b)(4) Trade Secret Process - Product Specs [redacted]

2.3 Letter-to-File

(b)(4) Trade Secret Process - Product Specs [redacted]

2.4 Materials

(b)(4) Trade Secret Process - Product Specs [redacted]

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

[redacted]

2.5 Device Listing

Attachment B contains the complete device listing for the STALIF C® and STALIF C® Ti.

2.6 Instrumentation Listing

Table 1 contains the surgical instrumentation listing for the modified STALIF C® and STALIF C® Ti.

Table 1: Instrument listing (All instruments cleared in K133200 and K120819)

Ref #	Finished Part #	Catalogue Description	Material(s)	Classification	Pt Contacting*
CAS0 0511	IN235/1	STALIF C Introducer G.A.	Stainless Steel: 17-4, 303, 304 and 316L per ISO 5832-1; Aluminum	II	A
CAS0 1272	IN235/1S	STALIF C Introducer G.A. (Depth Stops)	Stainless Steel: 17-4, 303, 304 and 316L per ISO 5832-1; Aluminum	II	A
CAS0 0516	IN236/2	STALIF C Slap Hammer	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	0
CAS0 1039	IN238/1S	STALIF C UJ Awl – Extra Short	Stainless Steel 17-4 and 302 per ISO 5832-1; Custom Stainless Steel 455 per ASTM A564; Silicone	I	A
CAS0 0874	IN239/1	4mm Awl Guide	Stainless Steel 17-4 per ASTM A564/A693	I	A
CRM 03891	IN241	STALIF C 2 Screw Introducer	Custom Stainless Steel 455 per ASTM A564	II	A
CRM 04067	IN250	Rongeur 3mm Bite	Stainless Steel 420 per ASTM F899	I	A
CAS0 0881	IN255/2	T10 Screw Driver	Custom Stainless Steel 455 per ASTM A564; SANTOPRENE; Silicone	I	A
CAS0 0882	IN281/2	UL T10 Screw Driver	Stainless Steel 17-4 and 302 per ISO 5832-1; Custom Stainless Steel 455 per ASTM A564; Silicone	I	A

CRM 04278	IN282	Screw Remover Sleeve	Stainless Steel 17-4 per ASTM A564/A693	I	A
CAS0 1042	IN283/1	Screw Remover - T10 Socket	Stainless Steel 17-4 per ASTM A564/A693; Custom Stainless Steel 455 per ASTM A564	I	A
CRM 04571	IN334/1	STALIF C Cage Tamp	Stainless Steel 17-4 per ASTM A564/A693	I	A
CAS0 1031	IN351/2	Guided Straight Awl	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS0 1030	IN357/1	STALIF T10 Ball Joint Screw Driver	Stainless Steel 17-4 per ASTM A564/A693; Custom Stainless Steel 455 per ASTM A564; Silicone	I	A
CAS0 1073-5.5	IN391	5.5mm Tapered Cervical Rasp - 14mm AP	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS0 1073-6.5	IN392	6.5mm Tapered Cervical Rasp - 14mm AP	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS0 1073-7.5	IN393	7.5mm Tapered Cervical Rasp - 14mm AP	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS0 1073-8.5	IN394	8.5mm Tapered Cervical Rasp - 14mm AP	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS0 1073-9.5	IN395	9.5mm Tapered Cervical Rasp - 14mm AP	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS0 1048	IN407	4mm UJ Awl	Stainless Steel 17-4 and 302 per ISO 5832-1; Custom Stainless Steel 455 per ASTM A564; Silicone	I	A
CAS0 1064	IN408	4mm Ball Joint Awl	Stainless Steel 17-4 per ASTM A564/A693; Custom Stainless Steel 455 per ASTM A564; Silicone	I	A
CAS0 1096	IN438	4mm Ball Joint Awl - Drill Tip	Stainless Steel 17-4 per ASTM A564/A693; Custom Stainless Steel 455 per ASTM A564; Silicone	I	A
CAS0 1246	IN460	STALIF C Awl Guide (Small Handle) - 4.5mm	Stainless Steel 17-4 per ASTM A564/A693	I	A
CAS0 1320-5.5	IN535	5.5mm Tapered Rasp – 14mm AP No Depth Stop	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS0 1320-6.5	IN536	6.5mm Tapered Rasp – 14mm AP No Depth Stop	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A

CAS01320-7.5	IN537	7.5mm Tapered Rasp – 14mm AP No Depth Stop	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS01320-8.5	IN538	8.5mm Tapered Rasp – 14mm AP No Depth Stop	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS01320-9.5	IN539	9.5mm Tapered Rasp – 14mm AP No Depth Stop	Stainless Steel 17-4 per ASTM A564/A693; Silicone	I	A
CAS01240	IN436	Guided Angled (Punch) Awl – 4.0mm	Stainless Steel 17-4 per ASTM A564/A693; Nitinol per ASTM F2063	I	A
CRM04948	IN243/1E	5.5mm STALIF C (14mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04949	IN244/1E	6.5mm STALIF C (14mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04950	IN245/1E	7.5mm STALIF C (14mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04951	IN246/1E	8.5mm STALIF C (14mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04952	IN247/1E	9.5mm STALIF C (14mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04953	IN329/1R	5.5mm STALIF C (14mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04954	IN330/1R	6.5mm STALIF C (14mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04955	IN331/1R	7.5mm STALIF C (14mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04956	IN332/1R	8.5mm STALIF C (14mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04957	IN333/1R	9.5mm STALIF C (14mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM04991	IN243/1	5.5mm STALIF C (14mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM04992	IN244/1	6.5mm STALIF C (14mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM04993	IN245/1	7.5mm STALIF C (14mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM04994	IN246/1	8.5mm STALIF C (14mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A

CRM 04995	IN247/1	9.5mm STALIF C (14mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 04996	IN478	10.5mm STALIF C (14mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 04997	IN479	11.5mm STALIF C (14mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 04999	IN329/1	5.5mm STALIF C (14mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05000	IN330/1	6.5mm STALIF C (14mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05001	IN331/1	7.5mm STALIF C (14mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05002	IN332/1	8.5mm STALIF C (14mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05003	IN333/1	9.5mm STALIF C (14mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05004	IN481	10.5mm STALIF C (14mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05005	IN482	11.5mm STALIF C (14mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05254	IN439	5.5mm STALIF C (12mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05255	IN440	6.5mm STALIF C (12mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05256	IN441	7.5mm STALIF C (12mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05257	IN442	8.5mm STALIF C (12mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05258	IN443	9.5mm STALIF C (12mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05259	IN444	10.5mm STALIF C (12mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05260	IN445	11.5mm STALIF C (12mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05262	IN447	5.5mm STALIF C (12mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A

CRM 05263	IN448	6.5mm STALIF C (12mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05264	IN449	7.5mm STALIF C (12mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05265	IN450	8.5mm STALIF C (12mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05266	IN451	9.5mm STALIF C (12mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05267	IN452	10.5mm STALIF C (12mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05268	IN453	11.5mm STALIF C (12mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05293	IN462	5.5mm STALIF C (16mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05294	IN463	6.5mm STALIF C (16mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05295	IN464	7.5mm STALIF C (16mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05296	IN465	8.5mm STALIF C (16mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05297	IN466	9.5mm STALIF C (16mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05298	IN467	10.5mm STALIF C (16mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05299	IN468	11.5mm STALIF C (16mm AP) Tapered Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05301	IN470	5.5mm STALIF C (16mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05302	IN471	6.5mm STALIF C (16mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05303	IN472	7.5mm STALIF C (16mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05304	IN473	8.5mm STALIF C (16mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05305	IN474	9.5mm STALIF C (16mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A

CRM 05306	IN475	10.5mm STALIF C (16mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05307	IN476	11.5mm STALIF C (16mm AP) Domed Trial	Titanium Alloy per ISO 5832-3	II	A
CRM 05325	IN484	5.5mm STALIF C (16mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05326	IN485	6.5mm STALIF C (16mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05327	IN486	7.5mm STALIF C (16mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05328	IN487	8.5mm STALIF C (16mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05329	IN488	9.5mm STALIF C (16mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05330	IN489	10.5mm STALIF C (16mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05331	IN490	11.5mm STALIF C (16mm AP) Tapered Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05333	IN492	5.5mm STALIF C (16mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05334	IN493	6.5mm STALIF C (16mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05335	IN494	7.5mm STALIF C (16mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05336	IN495	8.5mm STALIF C (16mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05337	IN496	9.5mm STALIF C (16mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05338	IN497	10.5mm STALIF C (16mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CRM 05339	IN498	11.5mm STALIF C (16mm AP) Domed Trial - No Depth Stop	Titanium Alloy per ISO 5832-3	II	A
CAS0 1292	IN525	STALIF C Tapered Trial Narrow Sizer, 6.5mm	Stainless Steel 17-4 per ASTM A564/A693	II	A

*ISO Definitions
0 = None
A = Limited Exposure (≤ 24 Hours)

B = Prolonged Exposure (24 Hours – 30 Days)
C = Permanent Contact (> 30 Days)

3. Indications for Use

The Indications for Use form (Form FDA 3881) is provided in **Attachment D**.

4. 510(k) Summary

Device Trade Name: STALIF C® and STALIF C® Ti

Manufacturer: Centinel Spine, Inc.
900 Airport Road, Suite 3B
West Chester, PA 19380

Contact: Mr. John Parry
Development Manager
Phone: (484) 887.8813

Prepared by: Mr. Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
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Washington, DC 20005
Phone: (202) 552-5800
jeggleton@mcra.com

Date Prepared: July 30, 2014

Classifications: 21 CFR §888.3080, Intervertebral Body Fusion Device.

Class: II

Product Codes: OVE

Indications For Use:
The STALIF C® and STALIF C® Ti devices are intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion. STALIF C® and STALIF C® Ti are intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Summary of Technological Characteristics:
STALIF C® is a radiolucent intervertebral body fusion cage with unicortical cancellous bone screws. It is intended to be used as an IBF cage without supplementary fixation. The cross section profile of the STALIF C® is similar to that of the vertebral body endplate

with central cavity that can be packed with autograft or allograft. STALIF C® is manufactured from PEEK-OPTIMA® LT1 with titanium alloy screws and X-ray marker wires manufactured from unalloyed Tantalum (ASTM F-560). The STALIF C® Ti is identical to this design with a titanium plasma spray coating on the device endplates.

The purpose of the subject 510(k) was to expand the indications to include use with allograft.

Predicate Device:
The subject STALIF C® and STALIF C® Ti intervertebral body fusion devices are substantially equivalent to predicate ANATOMIC PEEK™ CERVICAL FUSION SYSTEM (K130177) with respect to indications, design, function, and materials.

Substantial Equivalence:
STALIF C®, STALIF C® Ti and predicate ANATOMIC PEEK™ CERVICAL FUSION SYSTEM are similar in design, material, and indicated use, and are both cleared devices. They do differ in that the ANATOMIC PEEK™ is indicated for use with allogenic bone graft. A comprehensive, clinical literature review has been conducted to investigate the risks and benefits associated with using allogenic bone graft with the STALIF C®. The clinical literature suggests that there is a positive benefit associated with allograft with minimal risk.

Performance Testing:
A comprehensive, clinical literature review and PearlDiver reimbursement data have been provided to investigate the risks and benefits associated with using allogenic bone graft with the STALIF C®. No new mechanical tests were performed since there were no design changes to the device.

Conclusion:
The Centinel Spine STALIF C® and STALIF C® Ti have been modified to expand the indications to permit use with allograft. The 510(k) demonstrates substantial equivalence to predicate devices.

5. Allograft Justification

The use of allograft for interbody fusion has grown over the past decade as the use of autograft, primarily from the iliac crest has greatly declined. In fact, many surgeons no longer use iliac crest bone graft and will only fill the interbody cage with allograft. Centinel Spine has received identical feedback from surgeons. However, to gain an understanding of how frequently surgeons are using allograft with an interbody cage, an analysis was performed on all cervical procedures beginning in 2011 and the choice of bone grafting material.

The FDA has allowed allograft use in the cervical spine for decades when used with anterior cervical plates (e.g., allograft blocks). (b)(4) Trade Secret Process - Product Specs [redacted], interbody cages are finally being allowed to be used with allograft; therefore, allowing surgeons to use these cages on-label and allowing companies to properly train and market with this option.

A major benefit of allograft is that a second, bone-harvesting surgery from the donor is not required, and allograft tissue is not associated with a significant risk of disease transmission. (b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) [redacted]

Centinel Spine (b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted]

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[1] (b)(4) Trade Secret Process - Product Specs [redacted] osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2

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

[redacted]

5.2 *Literature Review*

Introduction:

This literature review was conducted in order to examine the published clinical results for the efficacy of allograft with intervertebral body fusion cages (specifically PEEK cages) in the treatment of cervical spine degenerative disc disease (DDD). Historically, PEEK cages have been cleared for use only with autogenous bone in the lumbar and cervical spine. (b)(4) Trade Secret Process - Product Specs [redacted] In order to provide an incremental level of valid scientific evidence, the published clinical results for fusion rates, efficacy outcomes, and safety with PEEK interbody devices filled with allograft are the subject of this review. Based upon the findings, the review concludes that PEEK cages filled with allograft provide a safe clinical alternative with comparable clinical outcomes for cervical spinal fusion procedures.

Article Search Methods:

A literature search was performed using PubMed to identify relevant (b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted]

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

[redacted]

Titles and abstracts were examined for eligibility criteria compliance, and full texts for articles complying with these criteria were retrieved for further review. When eligibility criteria were ambiguous in the abstract, the eligibility was assessed after review of the full article. References that missed due to keywords or search terms but were later discovered were added to the citation listing.

In addition to the above search inclusion/exclusion criteria, articles that presented data solely on femoral ring allograft packed with autograft were excluded as they don't provide evidence specific to the goal of this search. Articles that did not present or discuss clinical data and outcomes were also excluded. The table below documents the search terms and limits utilized to locate relevant literature.

Table 3: Search terms and criteria

	(b)(4) Trade Secret Process - Product Specs
Medline (PubMed)	[redacted]

The "Number of Hits" refers to the number of articles identified by PubMed for the various search terms. Each abstract was reviewed for relevancy at this time. If the article was deemed relevant or the abstract provided insufficient evidence to assess the nature of the article, the article was retrieved. The number of articles that were retrieved for a specific search phrase has been documented under "Number of Articles Retrieved". Duplicate articles were not retrieved and therefore not part of this tally. A listing of all the articles retrieved can be found in **Attachment E**. Below each reference is the abstract that was reviewed. **Attachment E** also displays all of the search hits and the reason for exclusion, if any. This document details the sponsor's decision making process and eliminates any biased placed into this review. Articles that were identified for review but were unable to be obtained due to journal subscription limitations have been *italicized*.

Subject of Articles for Review

Of the articles obtained through utilizing the above search, the following table provides a brief overview regarding the subject of each article.

Table 4: Overview of PubMed identified literature in which clinical data is presented

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

[redacted]

*From previous literature review

Autologous bone in the treatment of the spine

Fusion is a common procedure used to treat a variety of spine related diseases. Historically (b)(4) Trade Secret Process - Product Specs [redacted] the only graft material for interbody fusion cleared in FDA indications to date for spine fusion has been autologous iliac crest bone graft, despite significant complications associated with the harvest site [1]. These complications include chronic donor site pain, which, particularly in minimally invasive spine surgery, can sometimes be more pronounced than at the site of the spinal fusion. Traditionally, filling the bone defect or treatment site with autologous bone graft has resulted in excellent fusion outcomes in patients. However, the quality of donor bone may be inconsistent due to the age of the patient or comorbidities such as osteoporosis, and therefore result in a poor outcome that requires secondary operations for successful fusion [1, 2].

Allograft bone as a fusion material

Allograft has been proposed as a substitute for autograft and is commonly used in the clinic as a fusion material because of its chemical and structural similarities to native bone, plentiful availability, established safety, and long shelf life. Bone allografts have

the potential to be used for conditions which require replacing bone, from minor to major procedures. Cancellous allograft has been used to treat bone defects and to complement certain joint replacement surgeries without the serious donor site morbidities associated with autograft. Furthermore, allografts have been used successfully in a wide range of surgeries including ligament reconstructions, chondral and/or osteochondral transplantations for knee defects, and other periodontal osseous defects [4-7], in addition to the applications in orthopaedic trauma and spinal fusion [3, 8-13]. Several studies have also shown that allograft in combination with metallic implants to aid bone fixation improves clinical outcome [8, 14, 15]. In most cases, bone graft substitutes such as allograft bone are intended for use in conjunction with adjunctive load bearing instrumentation. Generally, within spinal surgery this instrumentation is in the form of plate/screw systems, rod/screw systems or interbody devices.

A major benefit of allograft is that bone harvesting from the donor is not required, and allograft tissue is not associated with a significant risk of disease transmission. A (b)(4) Trade Secret Process - Product Specs [redacted] Depending on the processing conditions, allograft is available in either a mineralized or demineralized form. (b)(4) Trade Secret Process - Product Specs [redacted]

Allograft in the cervical spine

The use of allograft and/or autograft as a fusion material for cervical fusion has been widely discussed. Anterior cervical discectomy and fusion (ACDF) is a commonly performed spinal procedure with a number of available grafting options available such as the use of autograft or allograft [18].

Allograft has been shown to provide excellent clinical results in ACDF. (b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted] The study did find that autograft had a statistically significant increased time to fusion as allogenic took longer to fuse. (b)(4) Trade Secret Process - Product Specs [redacted].

In this (b)(4) Trade Secret Process - Product Specs [redacted] randomized to the three groups and followed for an (b)(4) Trade Secret Process - Product Specs [redacted] (b)(4) Trade Secret Process - Product Specs All patients, regardless of assigned treatment group, exhibited (b)(4) Trade Secret Process - Product Specs [redacted] although none were severe problems.

The use of allograft (b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted]

Several studies have been conducted, retrospectively reviewing previous fusion procedures that incorporated allogenic bone grafts. (b)(4) Trade Secret Process - Product Specs [redacted] Multiple

studies found (b)(4) Trade Secret Process - Product Specs [redacted] The investigators did report that for posterior cervical and multi-level fusions, allograft did not perform as well as autograft, with autograft patients reporting higher fusion rates and lower rates of graft collapse. (b)(4) Trade Secret Process - Product Specs [redacted].

In another (b)(4) Trade Secret Process - Product Specs [redacted] Therefore, the author did not specify the exact allograft fusion rate. The grafts were used in combination with a Smith-Robinson approach, with or without plating.

(b)(4) Trade Secret Process - Product Specs [redacted] Indications for treatment included cervical Spondylosis, herniated cervical disc, or both with all procedures being performed similar to the Smith-Robinson technique. (b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted] Limitations to this study include retrospective data with lack of control groups, large differences in patient population sizes (b)(4) Trade Secret Process - Product Specs [redacted] lack of standardized metrics for evaluating success.

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

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

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

[redacted]

Total Disc Replacement and Plate Studies with Allograft Control Groups

Several studies have compared a total disc replacement (TDR) with an ACDF plus allograft control group. (b)(4) Trade Secret Process - Product Specs [redacted].

(b)(4) Trade Secret Process - Product Specs [redacted]

[redacted]

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

[redacted]

[redacted]

[redacted]

[redacted]

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

effective while promoting excellent clinical outcomes.

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

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

The use of platelet gel to improve the bone healing has been extensively investigated in a wide variety of procedures. (b)(4) Trade Secret Process - Product Specs [redacted]

Similar to platelet gel, pulsed electromagnetic field (PEMF) stimulation has been shown to improve results in non-union fractures by promoting fusion. In this (b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs [redacted]

Interbody devices

Interbody devices are widely used for both lumbar and cervical spinal fusion since they increase initial stability as well as disc height following surgery [37]. Interbody cages have been introduced for housing fusion materials, providing mechanical support for spinal fusion, and for lowering radiographic complications such as subsidence or migration. Currently, PEEK devices are cleared for use as partial vertebral body replacement devices and intervertebral body fusion devices. As vertebral body replacements, PEEK cages are cleared for use with autograft or allograft, while as intervertebral fusion devices are cleared only with autograft. While it's understood that a fusion is not always achieved in a patient requiring a vertebral body replacement, patients can still be treated with allograft bone in the anterior column of the spine. This suggests the safety profile has been established. This is further supported by VBR procedures, which can span up to five (5) levels filled with allograft bone. Besides these specific clearances, there has been significant historical use of PEEK devices as interbody fusion devices, in combination with allograft materials, and with acceptable clinical results.

Interbody cages are composed of sturdy, biocompatible materials, such as titanium, carbon fiber-reinforced polymer, and polyetheretherketone (PEEK), which support biological loading [1, 37]. Also common are structural pieces of cortical bone that offer both load bearing and theoretical incorporation with the host bone. Structural allograft interbody cages have geometrical limitations due to the geometrical variability of the donated bone, which is irregular in shape. Hence, it is more likely that a device of exact and consistent dimensions may be manufactured from a synthetic material, rather than being machined from donated allograft bone. Apart from inconsistent geometry, machined allograft is also brittle, which may increase the likelihood of breakage both intra-operatively and postoperatively. Geometrical limitations on the graft window in machined allograft cages may also limit the volume of bone graft, or bone graft substitute, that may be applied to promote fusion. Successful fusion is important for long-term stabilization of decompressed anatomy, and to avoid cage migration which can result in nerve root symptomatic compression which may require revision surgeries [38]. Currently machined allograft tissue for use in spinal applications, in the shape of typical cages, is cleared and regulated by CBER but no claims of boney fusion are made.

In the last decade, PEEK has received more attention in the literature as being the cage material of choice because it has a modulus of elasticity similar to bone and is radiolucent for x-ray and magnetic resonance imaging techniques [37]. The PEEK cage has demonstrated excellent fusion potential, improved cervical lordosis, and increased cross sectional area and height of the foramina [39-41]. PEEK cages are generally regarded as load bearing implants with consistently large graft windows to allow for large volumes of bone graft to support fusion across the joint. Fusion of one vertebra to the next is in part dependent on a sufficient quantity and quality of bone graft. Major advantages of

utilizing allograft bone in interbody devices are the reduced risk of donor site morbidity as well as increased options for graft availability depending on the clinical need [42].

Clinical Review of PEEK cages filled with allograft

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

[redacted]

5.3 *Biomechanical Justification*

This literature review has focused on the use of allograft in conjunction with interbody devices including PEEK cages. There is a design difference between basic PEEK cages

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

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

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

5.4 *Conclusion*

There is a significant clinical need for new treatment options for spinal fusion to reduce donor complications resulting from autograft [47]. A significant benefit to using allograft for spinal fusion interbody applications is the avoidance of complications resulting from harvesting iliac autograft while achieving the same fusion rates. (b)(4) Trade Secret Process - Product Specs

6. Substantial Equivalence Summary

The purpose of this Traditional 510(k) is to expand the indications for use to include the option of using allogenic bone graft in adjunct to the device to help facilitate fusion.

As demonstrated above, the use of allograft for interbody fusion has grown over the past decade as not only surgeons refuse to use iliac crest bone graft, but patients also refuse to endure the pain associated with iliac crest harvesting. In fact, many surgeons consider iliac crest harvesting archaic and only use allograft with interbody cages. The use of allograft within the interbody space is not new to FDA since allograft has been cleared for use with cervical plates, pedicle screw systems, vertebral body replacements, posterior cervical systems for decades. (b)(4) Trade Secret Process - Product Specs [redacted]

As described above, the use of allograft for interbody cages provides major benefit because a second, bone-harvesting surgery from the donor is not required, and allograft tissue is not associated with a significant risk of disease transmission. This benefit has been experienced by patients for anterior cervical plates for decades, and hopefully can be experienced by those patients receiving a STALIF C. (b)(4) Trade Secret Process - Product Specs [redacted] . Depending on the processing conditions, allograft is available in either a mineralized or demineralized form. Additionally, allograft is currently indicated for use in the spine with vertebral body replacements.

Table 8 provides a detailed comparison of the modified and predicate components.

(b)(4) Trade Secret Process - Product Specs [redacted]

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

[redacted]

As summarized in the table above, the modified device is substantially equivalent to the predicate device with respect to intended use, geometry, materials, and method of fixation. In addition, the information provided in Section 5 demonstrates that the modified indications for use pose no new safety or efficacy issues.

There is a design difference between basic PEEK cages and STALIF C® with regards to (b)(4) Trade Secret Process - Product Specs [redacted] In order to

characterize the relative performance of these two methods, a biomechanical study was performed (Section 5.3).

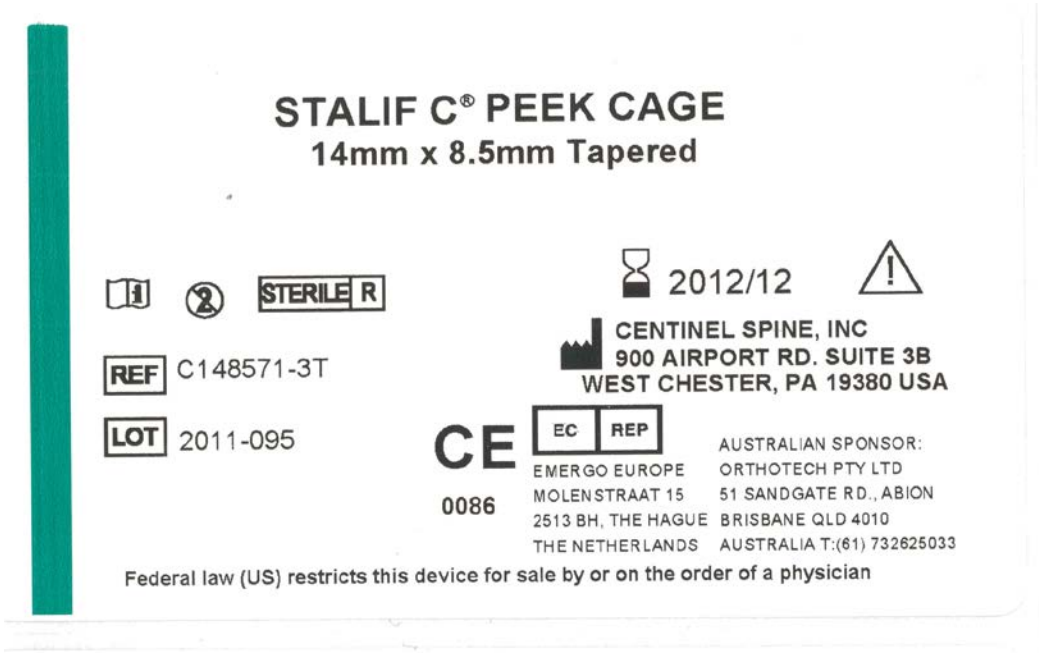
(b)(4) Trade Secret Process - Product Specs

[redacted]

7. Labeling: Label and Package Insert

7.1 Package Label

A representative outer package label is shown below.



7.2 Draft Surgical Technique Manual

A draft surgical technique manual for the STALIF C® is provided in **Attachment G**. The identical change to the STALIF C® Ti indications will be made to this manual.

7.3 Package Insert (IFU)

The draft IFU is presented in **Attachment H**. It is identical to the previously cleared IFU, except the indications have been modified to include the indications statement presented in this 510(k).

8. Sterilization

The sterilization and packaging process of the STALIF C® is identical to the predicate STALIF C™ cleared in K133200 and K120819. The STALIF C® is supplied sterile by gamma irradiation with a SAL of 10^{-6}. Dose mapping has been completed in accordance with ISO 11137-1 (Sterilization of health care products – Radiation- Part 1: Requirements for development, validation, and routine control of sterilization process for medical devices). Sterilization validation has been completed in accordance with AAMI TIR33:2005 (Sterilization of health care products – Radiation – substantiation of a selected sterilization dose- Method VD_{max}25 kGy as a sterilization dose – Method VD_{max}).

Reusable instrumentation is configured into sets and provided clean and non-sterile in a purpose designed anodized aluminum tray. Centinel's reusable surgical instruments have been validated in compliance with the requirements of AAMI TIR 30:2011. Document CRM04563 describes the safe processing requirements for Centinel's instruments and trays.

The proposed shelf life/expiration from the date of packaging is three years. In conjunction with real time aging study a three year accelerated aging study was conducted (VAL-2011-028) to ensure that validated pouch and tray sealing processes maintained product sterility over the intended shelf life of the products. Accelerated aging was carried out per ASTM F1980-07 on the packaged devices, which were then subjected to visual and functional verification.

9. Biocompatibility

The STALIF C® has two metallic X-ray marker wires manufactured from unalloyed Tantalum per ASTM F-560. The materials, Invibio PEEK-OPTIMA LT1 and Solvay Zeniva® PEEK, ASTM F2026-12; and titanium alloy (TI-6Al-4V), ISO 5832-3, are identical to the predicate devices (K133200, K120819, K072415). CP Ti powder (ASTM F1580) (b)(4) [redacted] The titanium alloy and the unalloyed tantalum have a long history of successful orthopedic use and well-established biocompatibility. Therefore, no new biocompatibility information is provided.

PEEK-OPTIMA® LT1 biocompatibility data from Invibio™ Ltd., has shown that biocompatibility is not a risk. Invibio™ Ltd., has authorized Centinel Spine permission for FDA (b)(4) [redacted]

10. Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Development Manager of Centinel Spine, Inc, I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been omitted.

_____

Mr. John Parry
Development Manager

7/30/2014

_____

Date

Premarket Notification [510(k)] Number: _____

11. Attachments

A. RTA Checklist

B. Device Listing

C. Engineering Drawings

D. Indications for Use Form (FDA Form 3881)

E. Literature Search Review

F. MAF Authorization Letters

G. Draft Surgical Technique Manual (STALIF C® and STALIF C® Ti)

H. Draft IFU

I. (b)(4) Trade Secret Process - Product Specs [redacted]

J. Predicate Clearance Letters

K. FDA Forms 3654

L. Letter to File

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Acceptance Checklist
for Traditional 510(k)s

Organizational Elements		
	Yes	**Page #**
a. Submission contains Table of Contents	☒	p. 14
b. Each section is labeled (e.g., heading or tabs designating Device Description section, Labeling section, etc.)	☒	all
c. All pages of submission are numbered	☒	all
d. Type of 510(k) is identified – traditional, abbreviated, or special	☒	1
Comments: n/a		

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		☒	☐	all
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet or 510(k) cover letter)		☒	☐	Sec. 1
		a.	Device trade name or proprietary name	☒	☐	
		b.	Device common name	☒	☐	
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☒	☐	
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109)		☒	☐	Att. D
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement		☒	☐	Sec. 4

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
		a.	Summary contains all elements per 21 CFR 807.92	☒	☐	
		b.	Statement contains all elements per 21 CFR 807.93	☐	☒	
		Comments:				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k)		☒	☐	Sec. 9
		Comments:				
	6.	Submission contains Class III Summary and Certification		☐	☒	
		Comments:				
	7.	Submission contains clinical data		☐	☒	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry – Financial Disclosure by Clinical Investigators*	☐	☒	
		b.	Submission includes completed Certification of Compliance with requirements of ClinicaTrials.gov Data Bank (FDA Form 3674) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not a "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☒	
		Comments: This submission does not contain clinical data in support of clearance.				
	8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654). *There should be a completed form for each referenced standard. Select "N/A" only if submission does not reference any standards.*		☒	☐	Att. I
		Comments:				
	9.	The submission identifies prior submissions for the same device for with FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior		☒	☐	CDRH Cover Sheet

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
		NSE determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F of the CDRH Coversheet form to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*				
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and statement of how or where in the submission this prior feedback is addressed.*	☐	☒	
		Comments:				
B.	**Device Description**					Sec. 2
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that applicable to the device, the submission includes the device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation.*	☐	☒	
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance.*	☐	☒	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
		Comments:				
	11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				Sec. 2
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☒	☐	Sec. 2
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	Att. G
		c.	A list and description of each device for which clearance is requested.	☒	☐	Att. B
		Comments:				
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *Select "N/A" if the submitter provides a rationale for why the submission does not contain engineering drawings.*		☒	☐	Att. C
		Comments:				
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system,		☒	☐	Sec. 2
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☒	☐	
		b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) for each component or accessory. *Select "N/A" if the component(s)/ accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☒	☐	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*	☒	☐	
		Comments:				
C.	**Substantial Equivalence Discussion**					

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
	14.	Submitter has identified a predicate(s) device		☒	☐	Sec. 6
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided.	☒	☐	Sec. 6
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐	Various
		Comments:				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				Sec. 6
		a.	Indications for Use	☒	☐	
		b.	Technology, including features, materials, and principles of operation	☒	☐	
		Comments:				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness.		☒	☐	Sec. 6
		Comments:				
D.	**Proposed Labeling (see also 21 CFR part 801)**					
	17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.		☒	☐	Sec. 7
		a.	Indications for use are stated in labeling are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☒	☐	Various
		b.	Submission includes directions for use that - Includes statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions,	☒	☐	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
			contraindications) AND - Includes direction for layperson OR submission states that the device qualifies for exemption per 21 CFR Subpart D			
		Comments:				
	18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol.		☒	☐	Sec. 7
		Comments:				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer or distributor (21 CFR 801.1)	☒	☐	Sec. 7
		b.	Labeling includes device common or usual name (21 CFR 801.61. *Select "N/A" if device is for prescription use only.*	☐	☒	
		Comments: The device is for prescription use only.				
	20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device specific requirements. *Select "N/A" if there are no applicable requirements in a device-specific regulation.*	☐	☒	
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance.*	☐	☒	
		c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide	☐	☒	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
			at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document.*			
		Comments:				
	21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	☒	
E.	**Sterilization**			☒	☐	Sec. 7
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☒ provided sterile ☒ provided non-sterile but sterilized by end user ☐ non-sterile when used This information will determine whether and what time of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.*					
	Comments: The sterilization specifications are provided in Section 8 of the submission.					
	22.	Assessment of the need for sterilization information				Sec. 7
		a.	Identification of device, and/or accessories, and/or components that provided sterile.	☒	☐	
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized.	☒	☐	
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☒	☐	
		Comments:				
	23.	If the device, and/or accessory, and/or component is provided sterile:		☒	☐	Sec. 7
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	☒	☐	
		b.	A description of the method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	☒	☐	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
			for each proposed sterilization method. *Note, the sterilization validation report is not required.*			
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if no sterilized using chemical sterilants.*	☐	☒	
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☒	☐	
		e.	Sterility Assurance Level (SAL) stated	☒	☐	
		Comments:				
	24.	If the device, and/or accessory, and/or component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized.*		☒	☐	Sec 7.
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.).	☒	☐	
		b.	A description of the method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.	☒	☐	
		c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☒	☐	
		d.	Submission includes sterilization instructions for end user	☒	☐	
		Comments:				
	25.	a.	If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device specific requirement. *Select "N/A" if there are no applicable requirements in a device-*	☐	☒	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
			specific regulation.			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance.*	☐	☒	
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document.*	☐	☒	
		Comments:				
F.	**Shelf Life**					
	26.		Proposed shelf life/expiration date stated. *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*	☒	☐	Sec. 7
		Comments:				
	27.		For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*	☒	☐	Sec. 7
		Comments:				
	28.		Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device	☒	☐	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**Page #**
		safety or effectiveness.			
		Comments:			
G.	**Biocompatibility**				
	Submission states that there: (*one of the below must be checked*) ☒ are ☐ are not direct or indirect (e.g., through fluid infusion) patient contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist.*				Sec. 8
	Comments:				
	29.	Submission includes list of patient-contacting device components and associated materials of construction, included identification of color additives, if present.	☒	☐	Sec. 2
		Comments:			
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☒	☐	Sec. 2
		Comments:			
	31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐	Sec. 8
		Comments:			
H.	**Software**				
	Submission states that the device: (*one of the below must be checked*) ☐ does ☒ does not contain software/firmware.				1

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**Page #**
	This information will determine whether an what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist.*				
	Comments:				
	32.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☒	
		Comments: **The submission does not contain software**.			
	33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submission for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☐	☒	
		Comments: **The submission does not contain software**			
I.	**EMC and Electrical Safety**				
	Submission states that the device: (*one of the below must be checked*) ☐ does ☒ does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist.*				1
	34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device specific standard), OR Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐	☒	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
		Comments: **The device does not require EMC or electrical safety evaluation.**				
	35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and, if applicable, the device-specific standard, OR Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).		☐	☒	
		Comments: **The device does not require EMC or electrical safety evaluation.**				
J.	**Performance Data - General**					
	36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/ evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☒	☐	N/A
		Comments: **No test reports included for modified indications.**				
	37.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation.*	☐	☒	
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative	☐	☒	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
			approach. *Select "N/A" if there is no applicable device-specific guidance.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document.*	☐	☒	
		Comments: There are no device-specific requirements.				
	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature.*		☒	☐	Sec. 5
		a.	Legible reprints or a summary of each article.	☒	☐	Sec. 5
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☒	☐	Sec. 5
		Comments: **Reprints of all cited literature are available upon request.**				
	39.	For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*		☐	☒	
		a.	Submission includes a study protocol which includes all elements outlined in 21 CFR 58.120	☐	☒	
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☒	
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study date provided to support a substantial	☐	☒	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
			equivalence determination.			
		Comments: There are no non-clinical reports included in this submission.				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐ is ☒ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					1
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
		a.	Precision/reproducibility	☐	☒	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☒	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☒	
		d.	Analytical specificity	☐	☒	
		Comments: This device is not an IVD.				
	41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation.*	☐	☒	
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable	☐	☒	

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** **Check "Yes" if item is present, "N/A" if it is not needed.** The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.				**Yes**	**N/A**	**Page #**
			statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document.*	☐	☒	
		Comments: There are no device-specific requirements.				

Table 1: Device Listing – All devices are Class II cleared in K120819

Ref	Catalogue Description	Size	Drawing Number	Patient Contacting?*
(b)(4)	STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 5.5MM	(b)(4)	
	STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 7.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 8.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 9.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 5.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 7.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 8.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 9.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 5.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 7.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 8.5MM		
	STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 9.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 5.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 7.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 8.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 9.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 5.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 7.5MM		

Ref	Catalogue Description	Size	Drawing Number	Patient Contacting?*
(b)(4)	STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 8.5MM	(b)(4)	
	STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 9.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 5.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 7.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 8.5MM		
	STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 9.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	12MM x 5.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	12MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	12MM x 7.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	12MM x 8.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	12MM x 9.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	14MM x 5.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	14MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	14MM x 7.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	14MM x 8.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	14MM x 9.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	16MM x 5.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	16MM x 6.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	16MM x 7.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	16MM x 8.5MM		
	STALIF C® PEEK CAGE 2 SCREW PARALLEL	16MM x 9.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 5.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 6.5MM		

Ref	Catalogue Description	Size	Drawing Number	Patient Contacting?*
(b)(4)	STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 7.5MM	(b)(4)	
	STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 8.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 9.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 10.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 11.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 5.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 6.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 7.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 8.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 9.5MM		
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	STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 11.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 5.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 6.5MM		
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	STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 9.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 10.5MM		
	STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 11.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 5.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 6.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 7.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 8.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 9.5MM		

Ref	Catalogue Description	Size	Drawing Number	Patient Contacting?*
(b)(4)	STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 10.5MM	(b)(4)	
	STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 11.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 5.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 6.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 7.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 8.5MM		
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	STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 10.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 11.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 5.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 6.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 7.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 8.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 9.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 10.5MM		
	STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 11.5MM		
	STALIF C® PEEK CAGE 3 SCREW PARALLEL	12MM x 5.5MM		
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	STALIF C® PEEK CAGE 3 SCREW PARALLEL	14MM x 6.5MM		
	STALIF C® PEEK CAGE 3 SCREW PARALLEL	14MM x 7.5MM		

Ref	Catalogue Description	Size	Drawing Number	Patient Contacting?*
(b)(4)	STALIF C® PEEK CAGE 3 SCREW PARALLEL	14MM x 8.5MM	(b)(4)	
	STALIF C® PEEK CAGE 3 SCREW PARALLEL	14MM x 9.5MM		
	STALIF C® PEEK CAGE 3 SCREW PARALLEL	16MM x 5.5MM		
	STALIF C® PEEK CAGE 3 SCREW PARALLEL	16MM x 6.5MM		
	STALIF C® PEEK CAGE 3 SCREW PARALLEL	16MM x 7.5MM		
	STALIF C® PEEK CAGE 3 SCREW PARALLEL	16MM x 8.5MM		
	STALIF C® PEEK CAGE 3 SCREW PARALLEL	16MM x 9.5MM		
	STALIF™ C Screws			
	STALIF C® 13mm Tapered Core T10 Screw (Ti)	4mm DIA		
	STALIF C® 13mm Parallel Core T10 Screw (Ti)	4mm DIA		
	STALIF C® PRIMARY T10 SCREW	4mm DIA		
	STALIF C® PRIMARY T10 SCREW	4mm DIA		
	STALIF C® PRIMARY T10 SCREW	4mm DIA		
	STALIF C® REVISION T10 SCREW	4mm DIA		
	STALIF C® REVISION T10 SCREW	4mm DIA		
	STALIF C® REVISION T10 SCREW	4mm DIA		
	STALIF C® 15mm Tapered Core T10 Screw (Ti)	4mm DIA		
	STALIF C® 17mm Tapered Core T10 Screw (Ti)	4mm DIA		
	STALIF C® 15mm Parallel Core T10 Screw (Ti)	4mm DIA		
	STALIF C® 17mm Parallel Core T10 Screw (Ti)	4mm DIA		
	STALIF C® 13mm Parallel Core T10 Screw (Ti)	4mm DIA		
	STALIF C® ABO™SCREW (Ti)	4.0MM DIA. x 13MM		
	STALIF C® ABO™SCREW (Ti)	4.0MM DIA. x 14MM		
	STALIF C® ABO™SCREW (Ti)	4.0MM DIA. x 15MM		

Ref	Catalogue Description	Size	Drawing Number	Patient Contacting?*
(b)(4)	STALIF C® ABO™SCREW (Ti)	4.0MM DIA. x 16MM	(b)(4)	
	STALIF C® ABO™SCREW (Ti)	4.0MM DIA. x 17MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.0MM DIA. x 13MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.0MM DIA. x 14MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.0MM DIA. x 15MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.0MM DIA. x 16MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.0MM DIA. x 17MM		
	STALIF C® ABO™SCREW (Ti)	4.5MM DIA. x 13MM		
	STALIF C® ABO™SCREW (Ti)	4.5MM DIA. x 14MM		
	STALIF C® ABO™SCREW (Ti)	4.5MM DIA. x 15MM		
	STALIF C® ABO™SCREW (Ti)	4.5MM DIA. x 16MM		
	STALIF C® ABO™SCREW (Ti)	4.5MM DIA. x 17MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.5MM DIA. x 13MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.5MM DIA. x 14MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.5MM DIA. x 15MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.5MM DIA. x 16MM		
	STALIF C® REVISION ABO™SCREW (Ti)	4.5MM DIA. x 17MM		
	STALIF™ C Trials			
	STALIF C® (12MM AP) TAPERED TRIALS	12MM x 5.5MM		
	STALIF C® (12MM AP) TAPERED TRIALS	12MM x 6.5MM		
	STALIF C® (12MM AP) TAPERED TRIALS	12MM x 7.5MM		
	STALIF C® (12MM AP) TAPERED TRIALS	12MM x 8.5MM		
	STALIF C® (12MM AP) TAPERED TRIALS	12MM x 9.5MM		
	STALIF C® (12MM AP) TAPERED TRIALS	12MM x 10.5MM		

Ref	Catalogue Description	Size	Drawing	Patient
(b)(4)	STALIF C® (12MM AP) TAPERED TRIALS	12MM x 11.5MM	(b)(4)	
	STALIF C® (12MM AP) DOMED TRIALS	12MM x 5.5MM		
	STALIF C® (12MM AP) DOMED TRIALS	12MM x 6.5MM		
	STALIF C® (12MM AP) DOMED TRIALS	12MM x 7.5MM		
	STALIF C® (12MM AP) DOMED TRIALS	12MM x 8.5MM		
	STALIF C® (12MM AP) DOMED TRIALS	12MM x 9.5MM		
	STALIF C® (12MM AP) DOMED TRIALS	12MM x 10.5MM		
	STALIF C® (12MM AP) DOMED TRIALS	12MM x 11.5MM		
	STALIF C® (14MM AP) TAPERED TRIALS	14MM x 5.5MM		
	STALIF C® (14MM AP) TAPERED TRIALS	14MM x 6.5MM		
	STALIF C® (14MM AP) TAPERED TRIALS	14MM x 7.5MM		
	STALIF C® (14MM AP) TAPERED TRIALS	14MM x 8.5MM		
	STALIF C® (14MM AP) TAPERED TRIALS	14MM x 9.5MM		
	STALIF C® (14MM AP) TAPERED TRIALS	14MM x 10.5MM		
	STALIF C® (14MM AP) TAPERED TRIALS	14MM x 11.5MM		
	STALIF C® (14MM AP) DOMED TRIALS	14MM x 5.5MM		
	STALIF C® (14MM AP) DOMED TRIALS	14MM x 6.5MM		
	STALIF C® (14MM AP) DOMED TRIALS	14MM x 7.5MM		
	STALIF C® (14MM AP) DOMED TRIALS	14MM x 8.5MM		
	STALIF C® (14MM AP) DOMED TRIALS	14MM x 9.5MM		
	STALIF C® (14MM AP) DOMED TRIALS	14MM x 10.5MM		
	STALIF C® (14MM AP) DOMED TRIALS	14MM x 11.5MM		
	STALIF C® (16MM AP) TAPERED TRIALS	16MM x 5.5MM		
	STALIF C® (16MM AP) TAPERED TRIALS	16MM x 6.5MM		

Ref	Catalogue Description	Size	Drawing Number	Patient Contacting?*
(b)(4)	STALIF C® (16MM AP) TAPERED TRIALS	16MM x 7.5MM	(b)(4)	
	STALIF C® (16MM AP) TAPERED TRIALS	16MM x 8.5MM		
	STALIF C® (16MM AP) TAPERED TRIALS	16MM x 9.5MM		
	STALIF C® (16MM AP) TAPERED TRIALS	16MM x 10.5MM		
	STALIF C® (16MM AP) TAPERED TRIALS	16MM x 11.5MM		
	STALIF C® (16MM AP) DOMED TRIALS	16MM x 5.5MM		
	STALIF C® (16MM AP) DOMED TRIALS	16MM x 6.5MM		
	STALIF C® (16MM AP) DOMED TRIALS	16MM x 7.5MM		
	STALIF C® (16MM AP) DOMED TRIALS	16MM x 8.5MM		
	STALIF C® (16MM AP) DOMED TRIALS	16MM x 9.5MM		
	STALIF C® (16MM AP) DOMED TRIALS	16MM x 10.5MM		
	STALIF C® (16MM AP) DOMED TRIALS	16MM x 11.5MM		

*ISO Definitions
0 = None
A = Limited Exposure (≤ 24 Hours)
B = Prolonged Exposure (24 Hours – 30 Days)
C = Permanent Contact (> 30 Days)

Table 1: All devices cleared in K133200 as Class II with >30 days body contact

Ref	Catalogue Description	Size	Drawing Number
(b)(4)	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 5.5MM	(b)(4)
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	12MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	14MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW TAPERED	16MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	12MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 5.5MM	

Ref	Catalogue Description	Size	Drawing Number
(b)(4)	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 6.5MM	(b)(4)
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	14MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 2 SCREW DOMED	16MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 10.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	12MM x 11.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 10.5MM	

Ref	Catalogue Description	Size	Drawing Number
(b)(4)	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	14MM x 11.5MM	(b)(4)
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 10.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW TAPERED	16MM x 11.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 10.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	12MM x 11.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 5.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 10.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	14MM x 11.5MM	

Ref	Catalogue Description	Size	Drawing Number
(b)(4)	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 5.5MM	(b)(4)
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 6.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 7.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 8.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 9.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 10.5MM	
	CP Ti Coated STALIF C® PEEK CAGE 3 SCREW DOMED	16MM x 11.5MM	

(b)(4) Trade Secret Process - Engineering Drawing

(b)(4) Trade Secret Process - Engineering Drawing

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(b)(4) Trade Secret Process - Engineering Drawing

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Unknown

Device Name
STALIF C® and STALIF C® Ti

Indications for Use *(Describe)*

The STALIF C® and STALIF C® Ti devices are intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion. STALIF C® and STALIF C® Ti are intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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this device may be necessary. The MR image quality of artifacts may be compromised if the area of interest is in the exact same area or relatively close to the position of the STALIF C® implant.

- The STALIF C® has not been evaluated for safety and compatibility in the MR environment. The STALIF C® has not been tested for heating or migration in the MR environment.

Rx Only Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Please refer to your sales representative for further information about this device.

Do not re-sterilize.

STERILE R Sterilized using irradiation

Do not reuse

Do not use if package is damaged

Centinel Spine, Inc
900 Airport Road,
Suite 3B
West Chester, PA 19380
USA
Tel: (1) 484-887-8810
www.centinelspine.com

CE 0086

Patents pending

Australian Sponsor:
Orthotech Pty Ltd
51 Sandgate Rd
Abion, Brisbane QLD 4010
Australia
Tel: (61) 7 3262 5033

EC REP Authorized Representative in Europe
(Regulatory affairs only)
Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands
Tel: (31) (0) 70 345-8570

STERILE R

Centinel Spine

INSTRUCTIONS FOR USE
STALIF C®

General Description
The STALIF C® is a radiolucent cervical intervertebral body fusion device that is fixed to the superior and inferior vertebral bodies with cancellous bone screws augmented with an anti back-out system (ABO™).

The graft containment cavity is filled with bone graft (autograft and/or allograft) material. STALIF C® is an Integrated Interbody fusion™ device and does not require supplementary fixation. The STALIF C® IBF system consists of varying heights and sagittal profiles to accommodate individual pathology and anatomical conditions.

The STALIF C® device is manufactured from polyetheretherketone (PEEK) to ASTM F2026. X-ray marker wires are manufactured from unalloyed Tantalum (Ta) per ASTM F-560.

Indications
The STALIF C® is intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion. STALIF C® is intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Contraindications

- Osteoporosis, sepsis
- Infection or inflammation at or near the operative site
- Fever of undetermined origin
- Allergy to implant materials
- Patient is unable or unwilling to follow post operative instructions
- Disease or condition which precludes the possibility of healing
- Prior fusion at the level to be treated
- Any conditions not described in the indications

Warnings and Precautions

- Patients with previous spinal surgery at the levels to be treated may not experience the same clinical outcomes as those without a previous surgery.
- Selection of an appropriately sized device for the patient is important and increases the likelihood of a satisfactory outcome.
- The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this type of device.
- Do not use if the package is damaged or opened. Contents may not be sterile.
- Do not use if current date exceeds label expiry date.
- Do not re-sterilize sterile implants.
- Instrumentation provided with the implants must be used in accordance with the approved surgical technique.
- Do not use excessive force when introducing and positioning the implant within the intervertebral body space to avoid damaging the implant.
- Re-usable surgical instruments must be re-sterilized prior to next use.
- Do not reuse the device even if the device shows no external signs of damage. Internal stresses from previous use may cause early failure.
- Should not be used with components of any other system or manufacturer.

Potential adverse effects with the STALIF C®

Potential risks or adverse effects identified with the use of this intervertebral body fusion device, which may require additional surgery are similar to those of other spinal systems, and include, but are not limited to:

- Early or late loosening of the components
- Bending or breakage of the components
- Foreign body (allergic) reaction
- Infection
- Pseudoarthrosis (i.e., non-union)
- Bone loss due to resorption or stress shielding
- Loss of neurological function
- Neurological difficulties such as radiculopathy, paresthesia, new or continued pain, numbness/tingling, neuroma, dural tears, neuropathy and neurologic deficit
- Loss or impairment of bowel, sexual, and/or bladder function
- Vascular damage resulting in excessive blood loss
- Bone graft complications including pain, fracture or wound healing problems
- Spinal cord impingement or damage
- Fracture, damage, degenerative changes or instability of any bone above and/or below the level of surgery
- Additional surgery
- Death

STALIF C®

Packaging

Packaging of the components should be intact upon receipt. Damaged packages or products should not be used, and should be returned to Centinel Spine.

Sterility

All components of the STALIF C® device are provided sterile for single use only. STALIF C® is supplied sterile by gamma irradiation with a SAL of 10^{-6}. Dose mapping has been completed in accordance with ISO 11137. Sterilization validation has been completed in accordance with AAMI TIR27 (VDmax method).

Instructions for Use

Use of the STALIF C® device should only be considered when the following pre-operative, intra-operative and post-operative conditions exist:

Pre-operative

- Patient meets the indication criteria described and does not have any contraindications.
- The surgeon should determine the construct prior to surgery to ensure that the required components in the necessary sizes are available.

Intra-operative

- The surgeon follows the surgical technique and instructions for use of the device. The surgical technique guide is available through Centinel Spine customer service.
- All components are inspected and determined to be free of damage.
- Once the STALIF C ® has been introduced and fixed by its screw fixation, additional anterior or posterior instrumentation is employed if deemed appropriate by the surgeon, who should consider factors such as the stability of the spinal column after fixation and potential risk associated with a subsequent surgical procedure to remove and/or replace these surgical appliances.
- Bone graft (autograft) is placed in the area to be fused.

Post-operative

- The choice to administer post-operative antibiotics is at the discretion of the surgeon.
- Post-operative mobilization and rehabilitation is at the discretion of the surgeon dependent on clinical and radiological progress.
- The need for external orthotic support is not mandatory with the final choice based on surgeon preference, patient condition and intra-operative findings that might influence implant security.
- The patient is to be instructed to reduce undue stress on the implant as a precaution to avoid clinical problems that could result in fixation failure.
- The patient is to be instructed to follow the post-operative regime.
- Optimization of MR imaging parameters to compensate for the presence of

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 8, 2014

Centinel Spine, Incorporated
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Justin Eggleton
Director, Spine Regulatory Affairs
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K133200
Trade/Device Name: STALIF C®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: April 7, 2014
Received: April 8, 2014

Dear Mr. Eggleton:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

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

Enclosure

4. Indications for Use

510(k) Number (if known): K133200

Device Name: STALIF C®

The STALIF C® is intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF C® is intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

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Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133200

Medtronic Sofamor Danek
ANATOMIC PEEK™ CERVICAL FUSION SYSTEM
510(k) Summary – K130177

September 2013

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

SEP 2 3 2013

Contact: **Lee Grant**
Distinguished Regulatory Affairs Advisor

Proposed Proprietary Trade Name: ANATOMIC PEEK™ CERVICAL FUSION SYSTEM

Classification Name(s): Intervertebral Body Fusion Device (per 21CFR Section 888.3080); Product Code: ODP

Description: The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is designed for use as a cervical interbody fusion device. The device is manufactured from polyetheretherketone (PEEK OPTIMA™) and is to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The ANATOMIC™ PEEK CERVICAL FUSION SYSTEM consists of hemi-cylindrical cages of various widths, heights and depths. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Indications for Use: The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK™ device is to be used with supplemental fixation. The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open anterior approach.

Summary of the Technological Characteristics: The purpose of this 510(k) submission is to seek clearance for the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative to autogenous bone graft. No changes have been made to the actual implants.

Identification of Legally Marketed Devices: The components contained in this application are identical to those cleared in K112444 (SE 11/15/11) with the exception of

the inclusion of allogenic cancellous and/or corticocancellous bone graft as an alternative bone graft material.

Discussion of Supporting Retrospective Clinical Data and Non-Clinical Testing: Published retrospective clinical data for the cervical interbody fusion devices similar to the ANATOMIC PEEK™ CERVICAL FUSION SYSTEM was provided in support of this application. The published clinical outcomes demonstrated that the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, in anterior cervical interbody fusion procedures to treat patients diagnosed with cervical disc disease as defined above poses no new risks to patients. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

Conclusion: The design features, materials used, manufacturing and sterilization methods are equivalent to the previously cleared ANATOMIC PEEK™ CERVICAL FUSION SYSTEM components with the exception of broadening the indications to include the aforementioned use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative graft material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 23, 2013

Medtronic Sofamor Danek USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K130177
Trade/Device Name: ANATOMIC PEEK™ Cervical Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: August 7, 2013
Received: August 14, 2013

Dear Mr. Grant:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

for

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130177

Device Name: ANATOMIC PEEK™ CERVICAL FUSION SYSTEM

Indications for Use:

The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK™ device is to be used with supplemental fixation. The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open anterior approach.

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)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

K120819

510(k) Summary

AUG 3 1 2012

Device Trade Name: STALIF C®

Manufacturer: Centinel Spine, Inc.
900 Airport Road, Suite 3B
West Chester, PA 19380

Contact: Mr. John Parry
Development Manager
Phone: (484) 887.8813
J.Parry@centinelspine.com

Prepared by: Mr. Justin Eggleton
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
Fax: (202) 552-5798

Date Prepared: May 4, 2012

Classifications: 21 CFR 888.3080, Intervertebral body fusion device

Class: II

Product Codes: OVE

Indications For Use:
The STALIF C® is intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF C® is intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

Device Description:
STALIF C® is a radiolucent intervertebral body fusion cage with unicortical cancellous bone screws. It is intended to be used as an IBF cage without supplementary fixation. The cross section profile of the STALIF C® is similar to that of the vertebral body endplate with central cavity that can be packed with autograft. STALIF C® is manufactured from PEEK-OPTIMA®

LT1 with titanium alloy screws and X-ray marker wires manufactured from unalloyed Tantalum (ASTM F-560).

Predicate Device:
The subject STALIF C® intervertebral body fusion device is substantially equivalent to predicate STALIF C™ (K072415), Stryker Spine Anchor-C Cervical Cage System (K102606), Spinal Elements Mosaic Cage (K071833), and the Medtronic Affinity Cages (P000028), with respect to indications, design, function, and materials.

Substantial Equivalence:
FEA simulation was performed on the worst case subject STALIF C® and predicate STALIF C™ to show the previous testing in K072415 was adequate. Additional mechanical testing per ASTM F2077 (e.g., static and dynamic compression, static and dynamic compression-shear, and static and dynamic torsion testing) was performed on the worst-case device. The results demonstrate that the acceptance criteria defined in the Design Control Activities Summary were met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Centinel Spine, Incorporated
% Mr. John Parry
Development Manager
900 Airport Road, Suite 3B
West Chester, Pennsylvania 19380

AUG 3 1 2012

Re: K120819
Trade/Device Name: STALIF C®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: August 02, 2012
Received: August 06, 2012

Dear Mr. Parry:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

4. Indications for Use

510(k) Number (if known): K120819

Device Name: STALIF C®

The STALIF C® is intended to be used as an intervertebral body fusion cage as a standalone system used with bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF C® is intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K120819

SURGICRAFT

510 (k) Summary – K072415

A	510(k) Owner	Surgicraft Limited 16 The Oaks Clews Road Redditch, Worchester England B98 7ST
	Contact	Donald W. Guthner Orgenix, LLC 111 Hill Road Douglassville, PA 19518 (646) 460-2984 (484) 363-5879 (FAX) dg@orgenix.com
	Preparation Date	December 7, 2007
B	Trade Name	STALIF™ C
	Common Name	Intervertebral Body Fusion Device, IBF Device
	Classification Name	Intervertebral Body Fusion Device
C	Predicate Device(s)	Substantial equivalence for the *Surgicraft STALIF™ C* is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices cleared under the following submissions: • P980048 S003 BAK/C Vista Cervical Interbody Fusion Device, Zimmer Spine, USA • P000028 AFFINITY Anterior Cervical Cage System, Medtronic Sofamor Danek, USA • K071833 Mosaic Device (a PEEK Cervical IBF device), Spinal Elements, Inc.

JAN 25 2008

Surgicraft Limited / 16 The Oaks / Clews Road / Redditch / Worcestershire / UK / B98 7ST
Tel: +44 (0)1527 512600 / Fax: +44 (0)1527 551166 / Customer Service Fax: +44 (0)1527 512612 / E-mail: info@surgicraft.co.uk
www.surgicraft.co.uk

D	Device Description	STALIF™ C is a radiolucent intervertebral body fusion device and unicortical cancellous bone screws and is intended to be used as an IBF cage without supplementary fixation. The cross section profile of the STALIF™ C is similar to that of the vertebral body endplate with a central cavity that can be packed with autograft. STALIF™ C is manufactured from PEEK-Optima^{R} LT1.
E	Intended Use	The STALIF C is intended to be used as an intervertebral body fusion cage as a stand alone system used with the bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF^{TM} C is intended to be used at one level. The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.
F	Technological Characteristics	As was established in this submission, the subject device is substantially equivalent to other devices cleared by the agency for commercial distribution in the United States. Engineering drawings, labeling, and mechanical testing have demonstrated that the subject device is substantially equivalent, if not identical, to its predicate devices in terms of design, materials of composition, indications for use, and such other characteristics as may be associated with the manufacture of any medical device.
G	Non-Clinical Testing	FDA Recognized Performance Standards ♦ ASTM 2077-03 ♦ ASTM F2267-04 ♦ ASTM F1877-98(03)
H	Clinical Testing	Not applicable to this device
I	Conclusions	Based on the 510(k) Summary and the information provided herein, we conclude that the *Surgicraft STALIF™ C* is substantially equivalent to the existing legally marketed devices under the Federal Food, Drug and Cosmetic Act.
J	Additional Information	NA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Surgicraft, Ltd
% Orgenix, LLC
Mr. Donald Guthner
111 Hill Road
Douglassville, PA 19518

Re: K072415
Trade/Device Name: Stalif™ C
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device (cervical)
Regulatory Class: II
Product Code: ODP
Dated: December 17, 2007
Received: December 19, 2007

Dear Mr. Gunther:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: STALIF™ C

Indications for Use:

The STALIF C is intended to be used as an intervertebral body fusion cage as a stand alone system used with the bone screws provided and requires no additional supplementary fixation systems. It is inserted between the vertebral bodies into the disc space from levels C2 to T1 for the treatment of cervical degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The device system is designed for use with autograft bone to facilitate fusion. STALIF™ C is intended to be used at one level.

The cervical cage is to be used in a skeletally mature patient who has had six weeks of non-operative treatment prior to implantation of the cage.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Page __ of ___

510(k) Number K072915

(b)(4) Trade Secret Process - Article

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(b)(4) Trade Secret Process - Article

(b)(4) Trade Secret Process - Article

(b)(4) Trade Secret Process - Article

(b)(4) Trade Secret Process - Article

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 5832-3:1996, Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy. 9/9/08

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-58	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-6:2007 Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation 5/5/10

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-120	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 11137-1:2006/(R) 2010, Sterilization of health care products-Radiation-Part 1: Requirements for development

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-297	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
AAMI/ANSI/ISO 11137-1:2006/(R) 2010, Sterilization of health care products-Radiation-Part 1: Requirements for development

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.2.2	Establishing the sterilization dose	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Option b) selected.

DESCRIPTION
Sterilization dose of 25kGy selected and substantiated.

JUSTIFICATION
Option previously used for company product.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
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 number.

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2007, Medical devices - Application of risk management to medical devices. 9/12/2007

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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

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

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

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

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

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

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

(b)(4) Trade Secret Process - Engineering Design

(b)(4) Trade Secret Process - Engineering Design

(b)(4) Trade Secret Process - Engineering Design

(b)(4) Trade Secret Process - Engineering Design