

510(k) Premarket Notification

**APR 15 2013**

CeSpace PEEK Intervertebral Body Fusion System (Plasmapore® Coated)

K123909

Page 1 of 3

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

**Aesculap® Implant Systems(AIS) – CeSpace XP Intervertebral Body Fusion System**

December 18, 2012

**COMPANY:** Aesculap® Implant Systems (AIS), LLC.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Lisa M. Boyle, Sr. Regulatory Affairs Specialist  
610-984-9274 (phone)  
610-791-6882 (fax)  
lisa.boyle@aesculap.com

**TRADE NAME:** AIS CeSpace XP Intervertebral Body Fusion System  
**COMMON NAME:** Intervertebral Body Fusion Device  
**CLASSIFICATION NAME:** Orthosis, Spinal Intervertebral Fusion  
**REGULATION NUMBER:** 888.3080  
**PRODUCT CODE:** ODP  
**REVIEW PANEL:** Orthopedics

**INDICATIONS FOR USE**

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

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## **DEVICE DESCRIPTION**

The Aesculap CeSpace XP Intervertebral Body Fusion System is a cervical intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of sizes to meet the requirements of the individual patient anatomy. Components are manufactured from PEEK – Optima LT1 (per ASTM F2026) with a titanium layer and a vacuum plasma spray coating (Plasmapore® - per ISO 5832-3). The device will have Tantalum markers per ASTM F-560.

## **TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The components of the CeSpace XP Intervertebral Body Fusion System are offered in the same range of shapes and sizes as the predicate device. The material used for the Aesculap® Implant Systems device is the same as that used to manufacture the predicate devices. The only difference between the predicate device and the subject device is the titanium layer and a vacuum plasma spray coating (Plasmapore®).

## **PERFORMANCE DATA**

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the AIS SIBD XP Spinal System is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic torsion per ASTM F2077
- Static and dynamic axial compression per ASTM F2077
- Shear resistance evaluation
- Subsidence per ASTM F2267

In addition to FDA's Spine Guidance, Aesculap has also completed non-clinical testing recommended in the "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements." The following tests were performed:

- Microstructure of the coating per ASTM F1854
- Static Tensile Strength per ASTM F1147
- Static Shear Strength per ASTM F1044
- Shear Fatigue Test per ASTM F1160
- Abrasion Resistance per ASTM F1978

The results of these tests showed that the CeSpace XP Spinal Implant System meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

## **SUBSTANTIAL EQUIVALENCE**

AIS believes that the Cespace XP Intervertebral Body Fusion System is substantially equivalent to the design of the Aesculap CeSpace PEEK VBR and Intervertebral Body

510(k) Premarket Notification

CeSpace PEEK Intervertebral Body Fusion  
System (Plasmapore® Coated)

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Fusion Systems (K083311). The Plasmapore® coating has been used and cleared in a number of legally marketed product lines manufactured by Aesculap (hip, knee, and spinal implants) for many years.



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

April 15, 2013

Aesculap Implant Systems, Incorporated  
% Ms. Lisa Boyle  
Senior Regulatory Affairs Specialist  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

Re: K123909

Trade/Device Name: Aesculap<sup>®</sup> Implant Systems (AIS) - CeSpace XP Intervertebral Body Fusion System

Regulation Number: 21 CFR 888.3080

Regulation Name: Intervertebral body fusion device

Regulatory Class: Class II

Product Code: ODP

Dated: March 13, 2013

Received: March 14, 2013

Dear Ms. Boyle:

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

Page 2 – Ms. Lisa Boyle

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" (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 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 D. Keith

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

Enclosure

510(k) Premarket Notification

CeSpace PEEK Intervertebral Body Fusion System (Plasmapore® Coated)

**A. INDICATIONS FOR USE STATEMENT**

**510(k) Number:** K123909

**Device Name: Aesculap® Implant Systems (AIS) – CeSpace XP Intervertebral Body Fusion System**

**Indications for Use:**

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

Prescription Use     X     and/or Over-the-Counter Use                       
(per 21 CFR 801.109)

(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



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

April 15, 2013

Aesculap Implant Systems, Incorporated  
% Ms. Lisa Boyle  
Senior Regulatory Affairs Specialist  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

Re: K123909

Trade/Device Name: Aesculap<sup>®</sup> Implant Systems (AIS) - CeSpace XP Intervertebral Body Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: ODP  
Dated: March 13, 2013  
Received: March 14, 2013

Dear Ms. Boyle:

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.

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Page 2 – Ms. Lisa Boyle

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Sincerely yours,

**Erin D. Keith**

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

Enclosure

Page 3 – Ms. Lisa Boyle

**Concurrence & Template History Page**  
 [THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: K123909

For Office of Compliance Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197.415881&\\_dad=portal&\\_schema=PORTAL&org=318](http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=318)

For Office of Surveillance and Biometrics Contact Information:

[http://insideportlets.fda.gov:9010/portal/page?\\_pageid=197.415881&\\_dad=portal&\\_schema=PORTAL&org=423](http://insideportlets.fda.gov:9010/portal/page?_pageid=197.415881&_dad=portal&_schema=PORTAL&org=423)

<b>Digital Signature Concurrence Table</b>	
Reviewer Sign-Off	Katherine Kavlock
Branch Chief Sign-Off	Anton Dmitriev
Division Sign-Off	Erin I. Keith  2013.04.15 16:03:56 -04'00'

f/t:KDK:tmj:4/15/13:eaf:4/15/13

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 <sup>st</sup> page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format

FAX HEADER 1:  
FAX HEADER 2:

TRANSMITTED/STORED : APR. 16. 2013 10:47AM	FILE MODE	OPTION	ADDRESS	RESULT	PAGE
4471 MEMORY TX			610+791+6882	OK	3/3

REASON FOR ERROR OR LINE FAIL  
 E-1) HANG UP  
 E-2) BUSY  
 E-3) NO ANSWER  
 E-4) NO FACSIMILE CONNECTION



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Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
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Dated: March 13, 2013  
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510(k) Premarket Notification

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**510(k) Number:**     K123909    

**Device Name: Aesculap® Implant Systems (AIS) – CeSpace XP Intervertebral Body Fusion System**

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(per 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD  
Division of Orthopedic Devices



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

February 19, 2013

AESCULAP IMPLANT SYSTEM, INC.  
3773 CORPORATE PARKWAY  
CENTER VALLEY, PENNSYLVANIA 18034  
ATTN: LISA M. BOYLE

510k Number: K123909  
Product: AESCULAP CESPAC XP  
On Hold As of 2/15/2013  
180th day is 8/14/2013

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

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

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Records processed under FOIA Request # 2013-9924. Released by CDRH on 10-29-2015

For further information regarding how various FDA and Industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

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

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

Sincerely yours,

Marjorie Shulman  
Director, 510(k) Program  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and Radiological Health

**Pugh, Dominique \***

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**From:** Pugh, Dominique \*  
**Sent:** Tuesday, February 19, 2013 10:20 AM  
**To:** lisa.boyle@aesculap.com  
**Cc:** DCCLetters  
**Subject:** K123909 HOLD LETTER  
**Attachments:** CrystalViewer[6].rtf

<b>Tracking:</b>	<b>Recipient</b>	<b>Delivery</b>
	lisa.boyle@aesculap.com	
	DCCLetters	Delivered: 2/19/2013 10:20 AM



**COVER SHEET MEMORANDUM**

**From:** Reviewer Name KATHERINE KAVLOCIK  
**Subject:** 510(k) Number K123909  
**To:** The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information for Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- NP NSE for lack of performance data
- NS NSE no response
- NL NSE for lack of performance data AND no response
- NM NSE pre-amendment device call for PMAs (515i)
- NC NSE post-amendment device requires PMAs
- NH NSE for new molecular entity requires PMA
- TR NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies only: Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age <= 21

Neonate/Newborn (Birth to 28 days)

Infant (29 days - < 2 years old)

Child (2 years - < 12 years old)

Adolescent (12 years - < 18 years old)

Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing; different protocol procedures, etc.)

Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <http://www.fda.gov/cdrh/comp/guidance/169.html>) Contact OC.

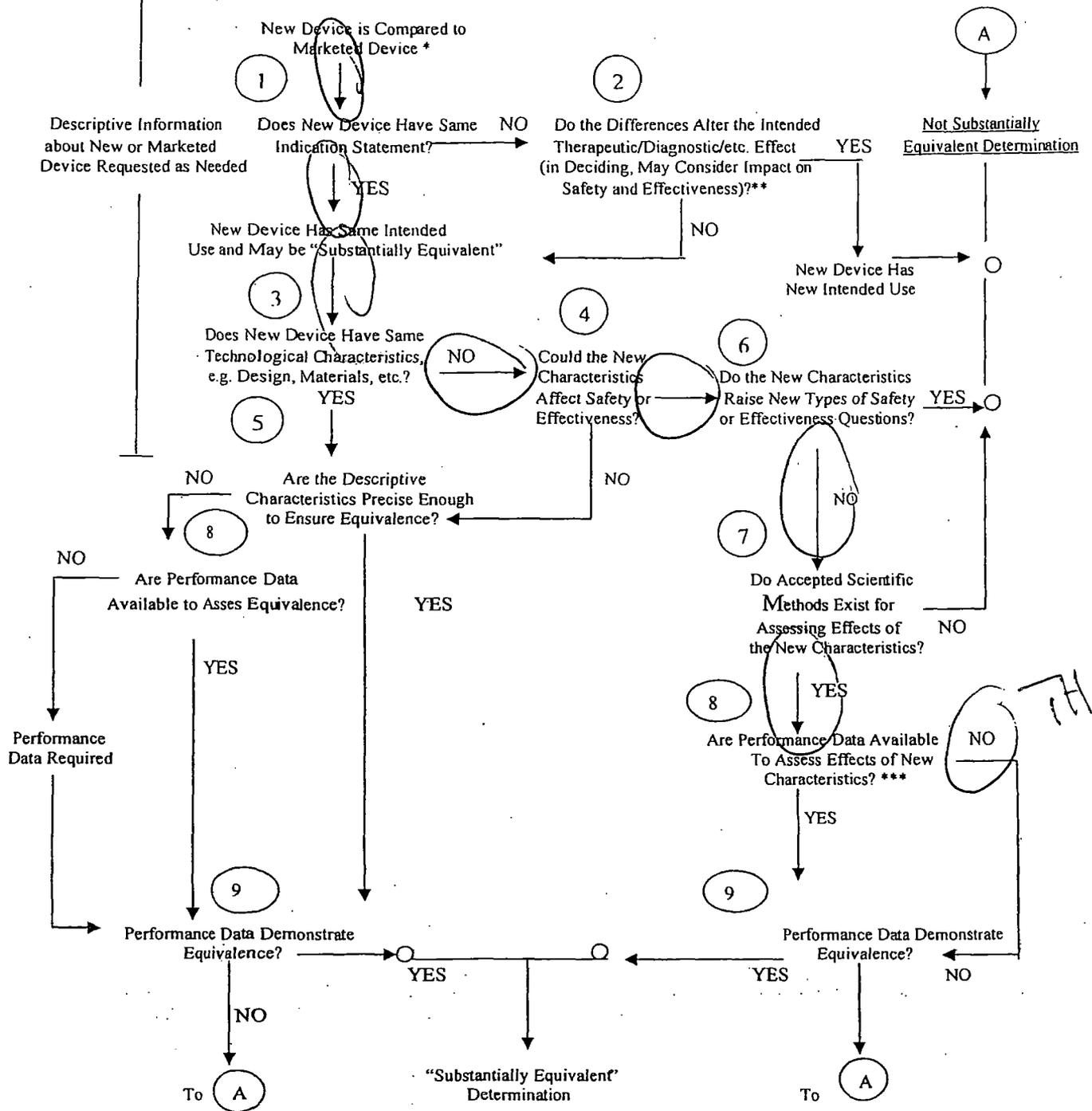
Regulation Number	Class*	Product Code
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(\*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:	<i>C. Redbold</i> (Branch Chief)	ASDB (Branch Code)	2/15/13 (Date)
Final Review:	<i>SB for MXM</i> (Division Director)		2/15/13 (Date)

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



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

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

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.



**DEPARTMENT OF HEALTH AND HUMAN SERVICES      MEMORANDUM**

Food and Drug Administration  
Office of Device Evaluation  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**Premarket Notification 510(k) Review  
Traditional**

**K123909**

Date: February 15, 2013  
To: The Record  
From: Katherine Kavlock, Biomedical Engineer

Office: ODE  
Division: DOD/ASDB

510(k) Holder: Aesculap Implant Systems, Inc  
Device Name: Aesculap CeSpace XP  
Contact: Lisa Boyle, Senior Regulatory Affairs Specialist  
Address: 3773 Corporate Parkway  
Center Valley, PA 18034  
Phone: 610.984.9274  
Fax: 610.791.6882  
Email: [lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com)

**Recommendation: Telephone Hold (TH)**

**I. Purpose and Submission Summary**

This 510(k) seeks to introduce into interstate commerce the Aesculap CeSpace XP into interstate commerce. The Aesculap CeSpace XP is a new version of the sponsor's previously cleared CeSpace PEEK spacer with an additional Ti coating (Plasmapore). The sponsor was previously asked to state the purpose of the coating (K111122) and they stated that they did not want to make any claims regarding bone in/on growth or osseointegration. However, the sponsor's website describes the coating as "osteoconductive" and the test reports indicate that the goal of the coating is to provide for better bone integration. The sponsor should again be asked to state the purpose of the coating and provide any additional relevant data to support the claims they wish to make (if any).

Additionally, the sponsor has not provided all the required performance testing. The sponsor will be asked to analyze their dynamic test solution for the presence of particulate and explain why the test results of the subject coated spacer are inferior to the predicate PEEK spacer or provide additional side-by-side testing. For the reasons listed above, I recommend that the Aesculap CeSpace XP spacer be put on **Telephone Hold (TH)** until the sponsor has provided the requested additional information.

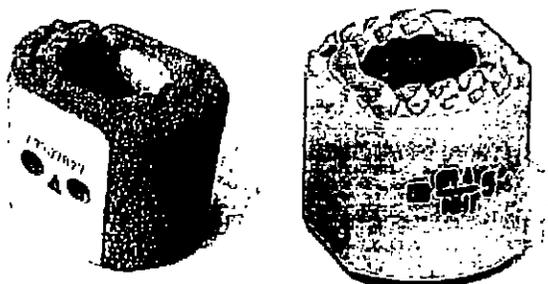
**II. Administrative Requirements**

		Yes	No	N/A
Indications for Use page (Indicate if: <b>Prescription</b> or OTC)	(Page 002)	X		
Truthful and Accuracy Statement	(Page 006)	X		
510(k) Summary or 510(k) Statement	(Page 003)	X		
Standards Form		X		

**III. Device Description**

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

The purpose of this 510(k) is to communicate the intent of Aesculap Implant Systems to market a new version of their PEEK cervical intervertebral body fusion device with a Ti coating.



**Figure 1:** CeSpace XP (subject device; left) and CeSpacer PEEK spacer (predicate device; right).

The subject CeSpace XP spacers are circular-shaped with a large central hole for placement of autogenous bone graft to encourage bony fusion through the construct. The superior and inferior surfaces have wedge teeth to minimize the risk of migration. These devices are manufactured from PEEK Optima-LT1 with tantalum radiographic markers and Ti coating. (b)(4)

(b)(4)

(b)(4) The coating is applied to all surfaces with the exception of the inserter attachment area and the inside of the central graft hole.

A table of system components with part numbers can be found in Section III (page 014) of the original submission. The sponsor proposes to offer the subject device in the following range of sizes:

- Footprint:* 14 mm x 11.5 mm or 16 mm x 13.5 mm
  - Heights:* 4 - 12 mm (1 mm increments)
  - Angulation:* 0° or 5°\*
- \*0° implants offered in 5-12 mm heights.

**Instruments**

The sponsor states that no new instruments are being introduced with the CeSpace XP implants. The system will utilize the existing CeSpace instruments cleared in K083311.

Engineering Drawings

Engineering drawings of the CeSpace XP implants are included in Section III (pages 016-019).

Materials

(b) (4)



**IV. Indications for Use**

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

(b)(4)



**V. Predicate Device Comparison**

The sponsor identified their own PEEK cervical spacer (CeSpace PEEK, K083311) and lumbar coated stand-alone cage (K111122) as the predicates for the subject device. The sponsor discussed substantial equivalence and provided a comparison table in Section 16 (pages 57-58) of the original submission (summarized below).

Property	CeSpace XP (subject device)	CeSpace PEEK (K083311)	SIBD XP Spinal System (K111122)
Indication for Use	The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are	The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are	

	<p>circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.</p> <p>***Also has VBR indications</p>	<p>circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.</p> <p>***Also has VBR indications</p>	
<b>Material</b>	PEEK Optima-LT1 cage with Plasmapore (Ti) coating	PEEK Optima-LT1	PEEK Optima-LT1 cage with Plasmapore (Ti) coating
<b>Footprint</b>	14 mm x 11.5mm 16 mm x 13.5 mm	14 mm x 11.5mm 16 mm x 13.5 mm	25 x 35 mm 29 x 40 mm
<b>Lordosis</b>	0 or 5°	0 or 5°	4, 9, and 14°
<b>Height</b>	4 - 12 mm	4 - 12 mm	10 - 20mm (2mm increments)
<b>Sterility</b>	Provided Sterile	Provided Sterile	Provided Sterile

**VI. Labeling**

(b) (4)



(b) (4)

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**VII. Sterilization/Shelf Life/Reuse**

(b)(4)

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**VIII. Biocompatibility**

The subject device components are manufactured from PEEK Optima-LT1 per ASTM F2026, Tantalum per ASTM F560, Ti Grade 2 per ISO 5832-2 and Titanium alloy (Ti-6Al-4V) per ISO 5832-3.

(b)(4)



**IX. Software**  
Not Applicable

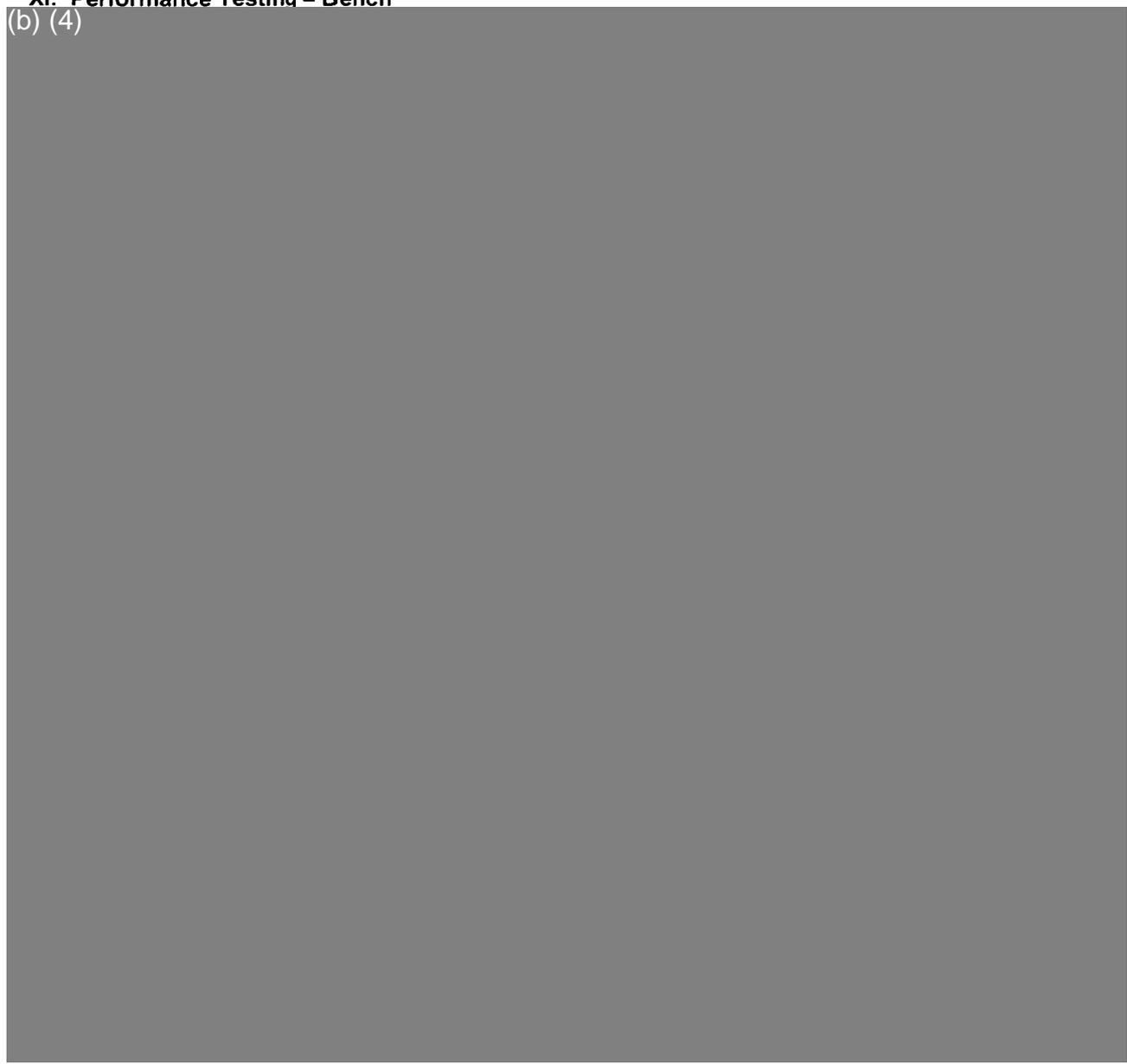
**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

(b) (4)



**XI. Performance Testing – Bench**

(b) (4)



(b) (4)



**XII. Performance Testing – Animal**

No animal data required at this time.

**XIII. Performance Testing – Clinical**

No clinical data required at this time.

**XIV. Substantial Equivalence Discussion**

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

1. Explain how the new indication differs from the predicate device's indication: *N/A*
2. Explain why there is or is not a new effect or safety or effectiveness issue: *N/A*
3. Describe the new technological characteristics:  
*The subject device contains a Ti coating called Plasmapore.*
4. Explain how new characteristics could or could not affect safety or effectiveness:  
*The subject device utilizes a titanium coating that may create new risks of wear or flaking not present in the predicate device.*
5. Explain how descriptive characteristics are not precise enough: *N/A*
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:  
*The subject device utilizes a plasma-sprayed titanium coating, which is commonly seen in orthopedic implants; however, with this coating, there is a risk that additional wear particulates may be formed in the event that fusion does not occur. This risk is present in other intervertebral cages that may have titanium-polymer interfaces; therefore, the questions of safety and effectiveness are not new to this device type.*
7. Explain why existing scientific methods can not be used: *N/A*
8. Explain what performance data is needed:  
*The sponsor should performed wear debris analysis in addition to mechanical testing per ASTM F2077.*
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *N/A*

(b) (4)



(b) (4)



Labeling

4. You submitted a draft package insert in an email sent 1/10/2013. However, the package insert provided does not contain all the necessary information. Please submit a revised draft package insert which addresses the following deficiencies:
  - a. Please clarify if the surgical technique manual is to be provided with the package insert. If not, please include a statement in the package insert indicating exactly how a surgical technique manual may be obtained.
  - b. Although you are not making any claims regarding MRI safety or conditionality within your submission, the Agency is concerned with burns, scars, and severe damage that may be caused due to heating and/or migration of devices within the MR environment. The Agency wants to ensure that MR safety information is most effectively communicated through appropriate labeling to medical personnel and patients. Although you are not making any specific claims for MRI safety or conditionality, it is important for end users to know that the subject device has not been evaluated for safety and/or compatibility in the MR environment. For this reason, please include the following statement in your draft package labeling: "The CeSpace XP implant has not been evaluated for safety and compatibility in the MR environment. The CeSpace XP implant has not been tested for heating or migration in the MR environment." In the future, if you want to make a specific claim for MR, please reference the 'Guidance for Industry & FDA Staff entitled Establishing Safety & Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment' regarding appropriate test data and information that should be included within your labeling and a future 510(k) submission.

**XVI. Contact History**

1/4/2013 - Email to sponsor requesting missing elements identified during RTA review.  
1/10/2013 - Email from sponsor with response to RTA Checklist  
2/15/2013 - Email to sponsor with Telephone Hold deficiencies

**XVII. Attachments**

Marketing brochure showing osteoconductive claims  
Sponsor response to RTA Checklist  
RTA Checklist

**XVIII. Recommendation**  
**Telephone Hold (TH)**

Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Codes: ODP

<b>Digital Signature Concurrence Table</b>	
Reviewer Sign-Off	Katherine D. Kaylock 2013.02.15 13:42:55 -05'00'
Branch Chief Sign-Off	
Division Sign-Off	

**Kavlock, Katherine**

---

**From:** Kavlock, Katherine  
**Sent:** Friday, February 15, 2013 1:41 PM  
**To:** LISA.BOYLE@AESCULAP.COM  
**Subject:** K123909 - Hold Deficiencies

**Importance:** High  
**Sensitivity:** Confidential

Dear Ms. Boyle,

I have completed my substantive review of your 510(k) premarket notification for modifications to the Aesculap CeSpace XP cervical intervertebral body fusion device, K123909. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete review of your submission we require that you address the following deficiencies:

(b) (4)



Please note that I have placed your file on telephone hold, which will remain effective until the Document Control Center receives responses to the deficiencies above. Please do not hesitate to contact me with any questions, comments or concerns.

Best Regards,

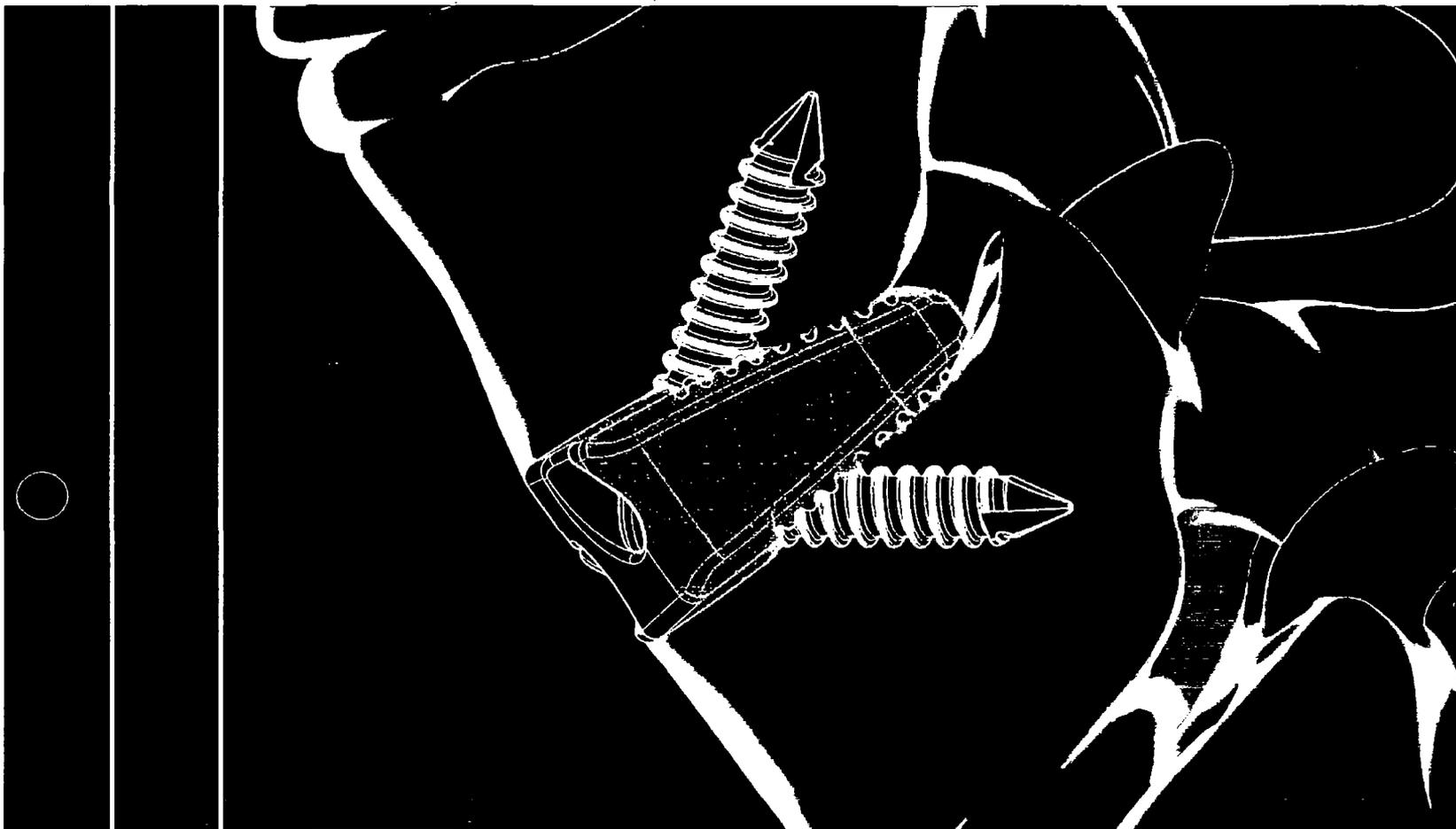
*Katherine Kavlock*, PhD  
Biomedical Engineer  
Anterior Spine Devices Branch (ASDB) NEW!\*  
U.S. Food & Drug Administration  
Phone: 301-796-7444  
Fax: 301-595-7851  
katherine.kavlock@fda.hhs.gov

-----  
\*Effective November 1, 2012, the Office of Device Evaluation (ODE) has implemented a new organizational structure. As a result of this reorganization, devices that affect the anterior column/vertebral body of the spine (e.g., intervertebral body fusion devices, vertebral body replacements, total disc replacements, anterolateral plates) fall under the jurisdiction of the Anterior Spine Devices Branch (ASDB), while devices that affect the posterior elements of the spine (e.g., pedicle screw systems, spinous process plates) fall under the jurisdiction of the Posterior Spine Devices Branch (PSDB).

-----  
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.

# Arcadius<sup>XP</sup>™ L Spinal System

Product Brochure



Aesculap Spine

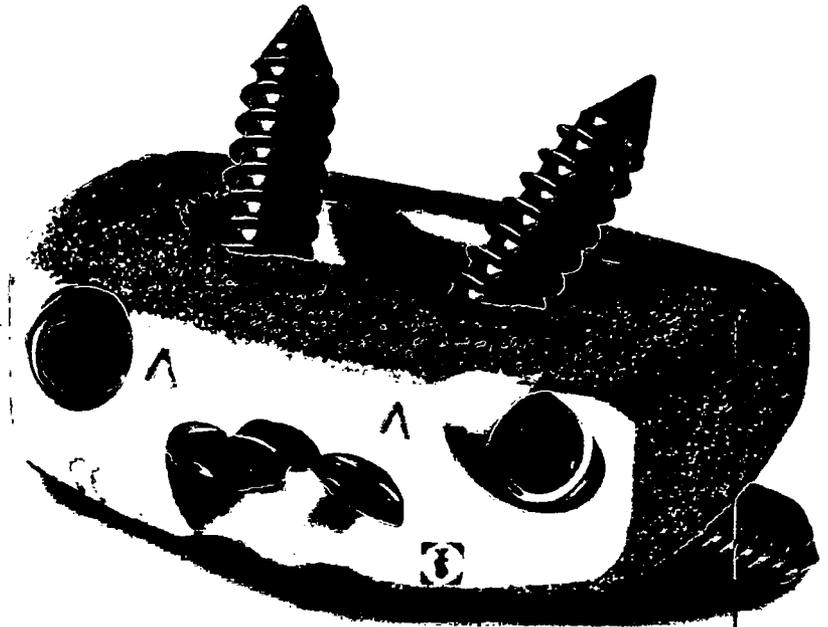
**AESCULAP.**  
Implant Systems

# A new fusion of speed and stability.

## Arcadius<sup>XP</sup>™ L Spinal System

The ideal combination of optimized stability, improved imaging properties, and operational simplicity, the Arcadius<sup>XP</sup> L is a unique interbody device offering an intuitive approach to ALIF procedures.

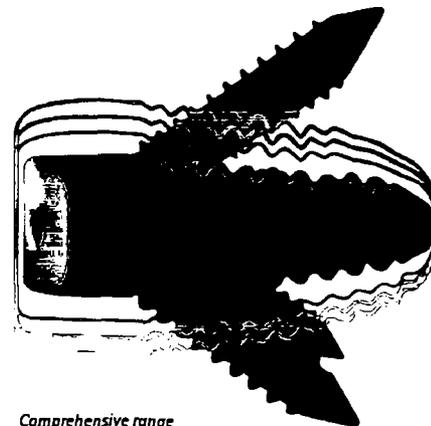
The Plasmapore<sup>XP</sup> osteoconductive coating enhances implant stability and improves imaging properties. A unique implant design and flexible instrumentation provide accessibility for screw insertion at all indicated levels and challenging patient anatomies.



*The Arcadius<sup>XP</sup> L is a unique stand alone interbody device with an osteoconductive coating.*

## Arcadius<sup>XP</sup> L System Features

- Plasmapore<sup>XP</sup> osteoconductive coating
- Wide variety of implant options
- Generous graft window
- Surface texturing
- X-Ray marker pins
- Midline accessibility for screw insertion
- Divergent screw design
- Dual locking mechanism with single-step activation
- Self-centering, self-drilling, and self-tapping bone screws
- Comprehensive array of instrumentation



*Comprehensive range of sizes allows an optimized fit.*

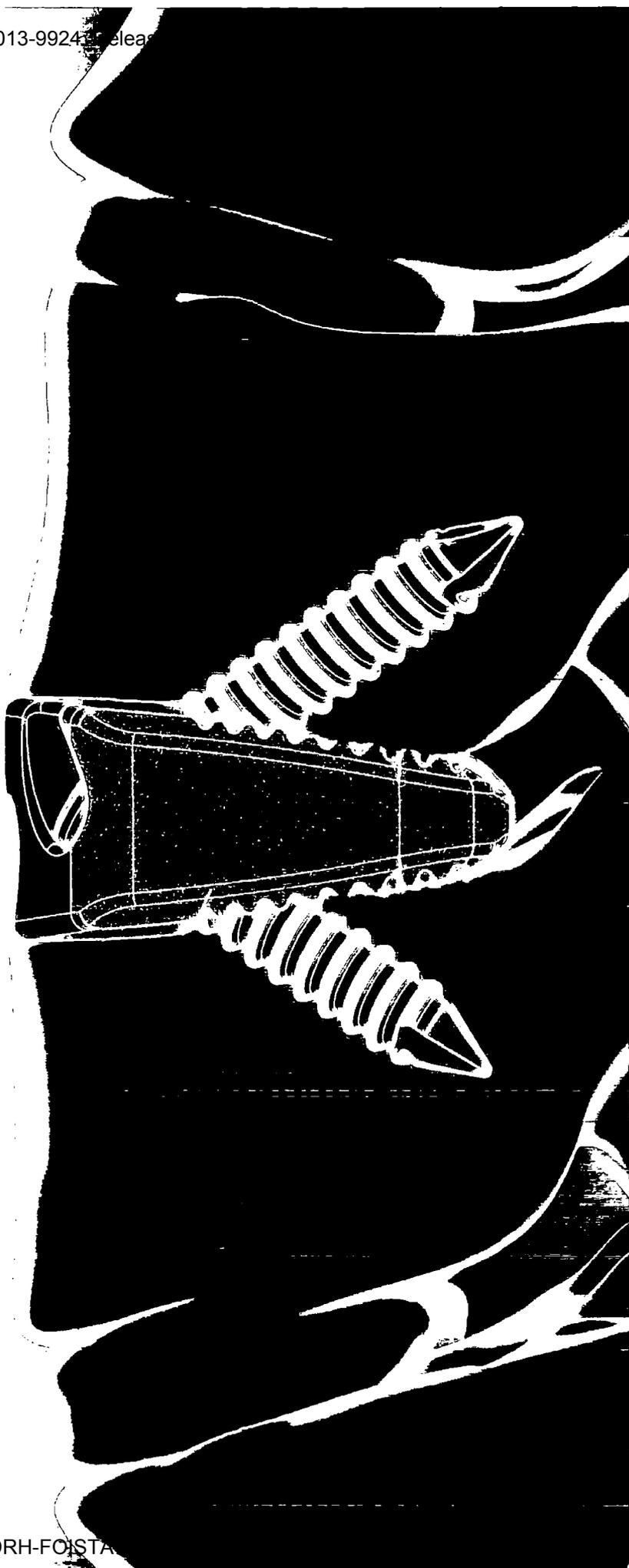
The Arcadius<sup>XP</sup> L is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1. For complete indications, contraindications, precautions, and warnings see inside back cover.

Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

## Built on experience.

The design advantages of the Arcadius<sup>XP</sup>™ L are the result of 30 years of innovation in spinal technology and 20 years of success in applying Plasmapore<sup>®</sup> coatings to Titanium orthopedic and spine implants:

- **Innovative Surface-Enhancing Technology:** Plasmapore<sup>XP</sup> is an osteoconductive pure Titanium porous coating with proven biocompatibility\*
- **Enhanced Stability:** The benefits of a stable divergent bone screw design plus the roughened surface area provided by Plasmapore<sup>XP</sup> coating deliver enhanced implant stability
- **Excellent Imaging Properties:** Plasmapore<sup>XP</sup> coating and X-Ray marker pins allow for improved visibility during imaging
- **Operational Simplicity:** Unique implant design and flexible instrumentation provide accessibility from all angles for ease in screw insertion
- **Optimized Implant Fit:** Wide variety of implant sizes ensures compatibility with varying patient anatomies



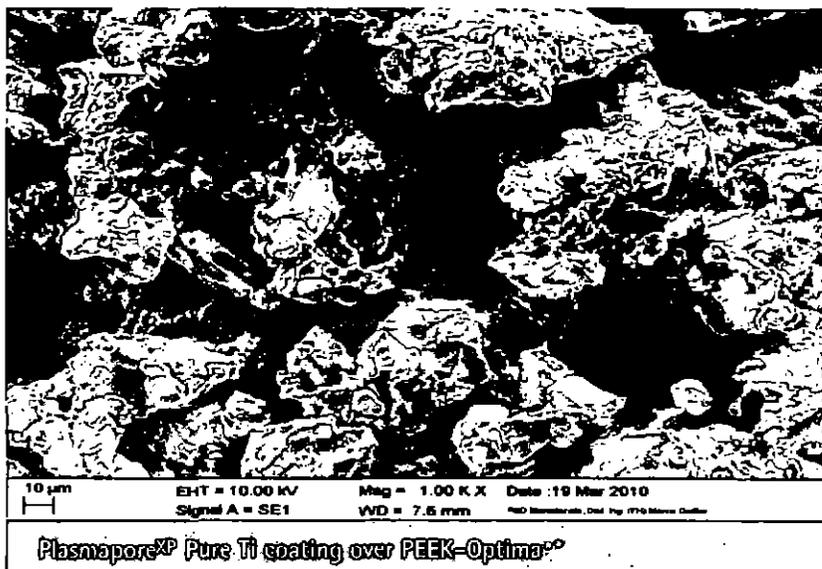
\*Data on file.

# Stability that starts on the surface.

## Plasmapore<sup>®XP</sup> Coating

The Arcadius<sup>™</sup> L is a stand alone ALIF device that features Plasmapore<sup>®XP</sup>, an osteoconductive pure Titanium porous coating:

- Surface-enhancing technology
- Proven biocompatibility
- Enhances implant stability
- Improves imaging properties



## Plasmapore<sup>®XP</sup>: A Surface-Enhancing Technology

A limitation of PEEK is that it has little direct bone contact. Aesculap has developed a way to complement the PEEK interbody implant with a surface-enhancing osteoconductive technology, Plasmapore<sup>®XP</sup>:

- The roughened surface provides several benefits that lead to improved implant stability:
  - Allows a greater surface area of the implant to be in direct contact with bone, which leads to higher mechanical strength
  - Increases migration resistance of the PEEK interbody implant.
- Plasmapore<sup>®XP</sup> coating has a high adhesion strength to PEEK:
  - Mechanical testing studies reveal that the adhesion strength of Plasmapore<sup>®XP</sup> to PEEK exceeds the shear and tensile strength of PEEK<sup>\*\*</sup>

<sup>\*\*</sup>PEEK-Optima is a registered trademark of InVivo Biomaterial Solutions.

# Easier to see.



*X-Ray images provided courtesy of Jeffrey A. Kozak, MD.*

## Excellent Imaging Properties

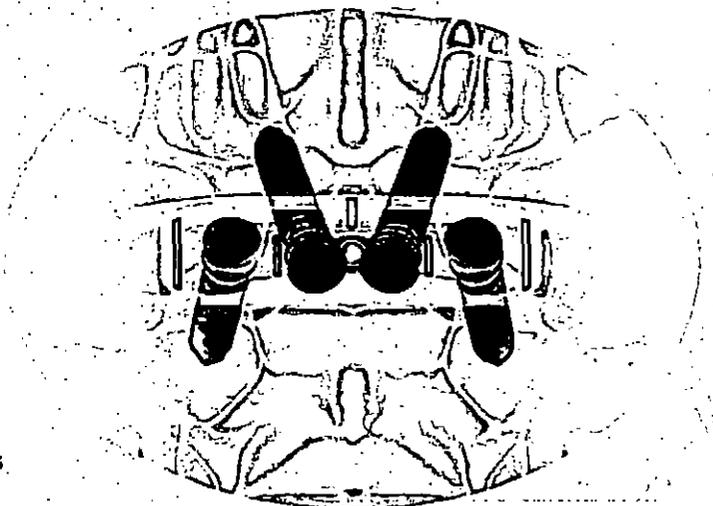
The combination of the Plasmapore<sup>XP</sup> coating and X-Ray marker pins allows for improved visibility during imaging:

- PEEK is a radiolucent material, allowing for visualization of bone growth adjacent to the implant; Plasmapore<sup>XP</sup> allows for clear delineation of implant contours during imaging
- 5 X-Ray marker pins allow for intraoperative positioning and verification
- Plasmapore<sup>XP</sup> provides excellent visibility and does not create any artifacts in CT or MRI
- Zero-profile implant design maintains excellent imaging properties in both AP and lateral views

## Enhanced Stability

Enhanced stability is provided by combining the benefits of the divergent bone screw design with the roughened surface of Plasmapore<sup>XP</sup>:

- **Divergent Screw Design:** It has been shown that implants with divergent screw designs offer more stability than implants with convergent screw designs in lateral bending, extension, and axial rotation
- **Increased Migration Resistance:** Testing has proven that the addition of the Plasmapore<sup>XP</sup> coating increases resistance to expulsion of the PEEK implant\*\*
- **Higher Mechanical Strength:** The roughness of the Plasmapore<sup>XP</sup> coating allows a greater surface area of the implant to be in direct contact with bone



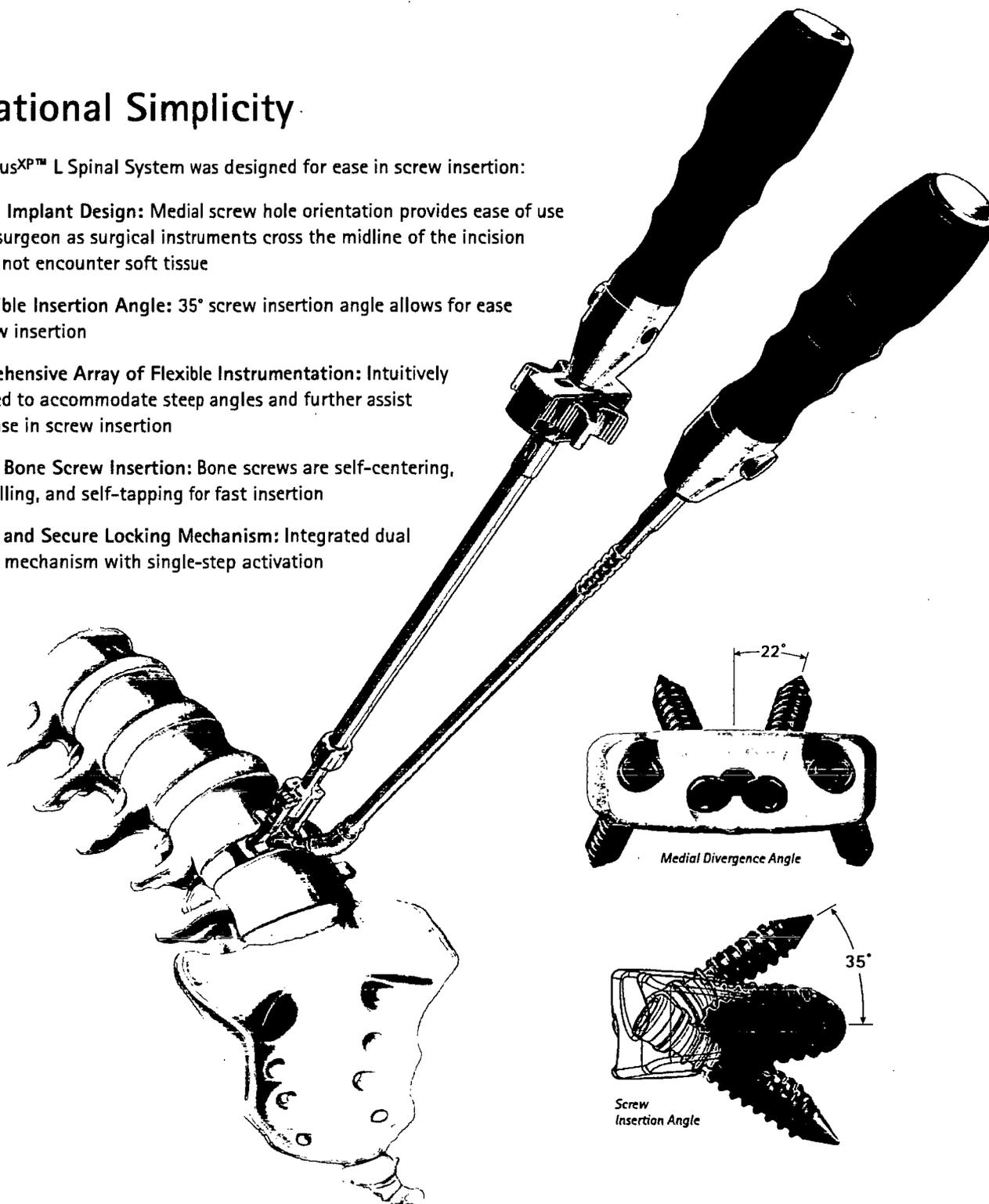
\*\*Data on file.

# Innovation from every angle.

## Operational Simplicity

The Arcadius<sup>XP</sup>™ L Spinal System was designed for ease in screw insertion:

- **Unique Implant Design:** Medial screw hole orientation provides ease of use to the surgeon as surgical instruments cross the midline of the incision and do not encounter soft tissue
- **Accessible Insertion Angle:** 35° screw insertion angle allows for ease in screw insertion
- **Comprehensive Array of Flexible Instrumentation:** Intuitively designed to accommodate steep angles and further assist with ease in screw insertion
- **Simple Bone Screw Insertion:** Bone screws are self-centering, self-drilling, and self-tapping for fast insertion
- **Simple and Secure Locking Mechanism:** Integrated dual locking mechanism with single-step activation



## Optimized Implant Fit

The Arcadius<sup>XP</sup> L implants were designed to provide an optimized implant fit:

- Intrinsic design does not add profile to the anterior border of the vertebral body
- Wide variety of implant options meets the requirements of varying patient anatomies
- Implants are available in two footprints, six heights, and three lordotic angles

### Implant Options

Lordotic Angle (°)	Height (mm)	Item Number	
		25mm x 35mm	29mm x 40mm
4	10	SO810P	SO825P
	12	SO812P	SO827P
	14	SO814P	SO829P
	16	SO816P	SO831P
	18	SO818P	SO833P
	20	SO820P	SO835P
9	10	SO840P	SO855P
	12	SO842P	SO857P
	14	SO844P	SO859P
	16	SO846P	SO861P
	18	SO848P	SO863P
	20	SO850P	SO865P
14	10	SO870P	SO885P
	12	SO872P	SO887P
	14	SO874P	SO889P
	16	SO876P	SO891P
	18	SO878P	SO893P
	20	SO880P	SO895P



Visit [aesculapimplantsystems.com/Arcadius](http://aesculapimplantsystems.com/Arcadius) today and experience a new era of interbody fusion.

### Indications & Contraindications

#### Indications & Intended Use

- Intended to be used with four bone screws if no supplemental fixation is used
- Indicated as an Intervertebral body fusion device designed for use with autograft
- Intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1
- Indicated for use in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).
- Patients should be skeletally mature and have undergone a regimen of at least six months of non-operative treatment prior to being treated with the Aesculap Implant Systems device

#### Contraindications

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the Arcadius<sup>XP</sup> L Spinal System
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of cooperation by the patient
- All cases that are not listed under indications

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Phone 866-229-3002 | Fax 610-984-9096 | [www.aesculapimplantsystems.com](http://www.aesculapimplantsystems.com)

Aesculap Implant Systems, LLC - a B. Braun company

DOC1063 2M 02/13

Questions? Contact FDA/CDRH/OCE/DID at [CDRH-FOISTATUS@fda.hhs.gov](mailto:CDRH-FOISTATUS@fda.hhs.gov) or 301-796-8118

**Kavlock, Katherine**

---

**From:** Lisa.Boyle@aesculap.com  
**Sent:** Thursday, January 10, 2013 9:06 AM  
**To:** Kavlock, Katherine  
**Subject:** RE: K123909 was not Reviewed  
**Attachments:** CeSpace XP RTA RESPONSE 01\_09\_13.pdf

Hi Kate,

attached please find the responses to the RTA checklist.

Please let me know if you need anything else.

Thanks,

Lisa

\*\*\*\*\*

Lisa Boyle  
Senior Regulatory Affairs Specialist

Aesculap Implant Systems, LLC.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Phone: (610) 984-9274  
Cell: (610) 295-7984  
Fax: (610)791-6882  
e-mail: lisa.boyle@aesculap.com

From: "Kavlock, Katherine" <Katherine.Kavlock@fda.hhs.gov>  
To: "LISA.BOYLE@AESCULAP.COM" <LISA.BOYLE@AESCULAP.COM>  
Date: 01/04/2013 02:02 PM  
Subject: RE: K123909 was not Reviewed

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Dear Ms. Boyle,

I apologize for the automatic email that you received yesterday. This email was sent prematurely in error as we have completed the administrative acceptance review of your premarket notification (510(k)) submission K123909. Our acceptance review indicates that your 510(k) submission does not meet the criteria established for administrative completeness.

However, our Refuse to Accept (RTA) policy has been implemented only for files received in 2013 and therefore, we have begun our substantive review of your 510(k) submission and we are requesting the missing information interactively.

Please refer to the attached checklist and e-mail your response to me referencing the 510(k) number K123909 by January 11, 2013. Your response should address all of the elements identified as missing or inconsistent in the attached checklist. Failure to provide the requested information by January 11, 2013 may result in placing the file on hold.

Upon receipt of the requested information, FDA may have additional requests for information.

Should you have questions about this email, please do not hesitate to contact me at the phone number or email listed below.

Thank you,  
Kate Kavlock

*Katherine Kavlock, PhD*  
Biomedical Engineer  
Anterior Spine Devices Branch (ASDB) **NEW!\***  
U.S. Food & Drug Administration  
Phone: 301-796-7444  
Fax: 301-595-7851  
katherine.kavlock@fda.hhs.gov

-----  
\*Effective November 1, 2012, the Office of Device Evaluation (ODE) has implemented a new organizational structure. As a result of this reorganization, devices that affect the anterior column/vertebral body of the spine (e.g., intervertebral body fusion devices, vertebral body replacements, total disc replacements, anterolateral plates) fall under the jurisdiction of the Anterior Spine Devices Branch (ASDB), while devices that affect the posterior elements of the spine (e.g., pedicle screw systems, spinous process plates) fall under the jurisdiction of the Posterior Spine Devices Branch (PSDB).

-----  
THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.

---

**From:** Katherine Kavlock [<mailto:katherine.kavlock@fda.hhs.gov>]  
**Sent:** Thursday, January 03, 2013 2:00 AM  
**To:** LISA.BOYLE@AESCULAP.COM  
**Cc:** Kavlock, Katherine  
**Subject:** K123909 was not Reviewed

January 3, 2013

### **Acceptance Review Notification - Review not Completed**

We were unable to conduct an administrative acceptance review on your premarket notification (510(k)) submission K123909 in a timely manner.

Therefore, we will proceed with the substantive review of your submission.

We will contact you during the course of the substantive review

should we require any additional information, including elements from the acceptance review.

Should you have questions about this email you may contact Katherine Kavlock,

the lead reviewer assigned to your submission.

[attachment "K123909 RTA Checklist.pdf" deleted by Lisa Boyle/BBMUS/BBRAUN]

\*\*\*\*\*  
 The information contained in this communication is confidential, may be attorney-client privileged, may constitute inside information, and is intended only for the use of the addressee. It is the property of the company of the sender of this e-mail. Unauthorized use, disclosure, or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify us immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.  
 \*\*\*\*\*



January 10, 2013

Ms. Katherine Kavlock  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Springs, MD 20993-0002

Re: K123909 – CeSpace PEEK XP

Dear Ms. Kavlock,

Below please find the missing information that FDA has requested via e-mail per the Refuse to Accept Checklist received on 01/04/2013.

**A. Administrative:**

**1** – A translation table related to the drawings has been included for your reference. The translation table can be found in Attachment A.

**D. Proposed Labeling**

**17(b)** – The surgical technique (ST) has been updated to include the warnings and precautions from the Instructions for Use (IFU). Please see Attachment B for revised copies of both the IFU and ST.

**18** – For sterile devices, the prescriptive use statement is always printed on the box of the device and can be found in the IFU as well.

**20(c)** – A copy of the revised labeling (IFU and Surgical Technique Guide) can be found in Attachment B.

**E. Sterilization**

**22(c)** – There are no new device specific instruments being proposed in the subject submission. The instruments used with this system has been reviewed in the original submission (K083311). The cleaning instructions/ sterilization parameters for the existing instruments have already been validated and are available on file.

**24(d)** – see response above to 22(c).

Aesculap Implant Systems, LLC  
3773 Corporate Parkway  
Center Valley, PA 18034  
Phone: 800-234-9179  
www.aesculapimplantsystems.com

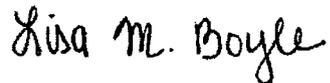
Aesculap Implant Systems, LLC - a B. Braun company

**F. Shelf Life**

**28** – The coating is made out of the same material (plasma sprayed titanium ) as the predicate devices on the market that contain Plasmapore® (AIS SIBD XP System (K111122) and the AIS Hydrofitt VBR System (K083186). It is not expected to degrade or change because of aging or storage conditions

If you have any questions or require additional information, please do not hesitate to contact me directly via phone at (610) 984-9274 or e-mail at [lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com).

Sincerely,



Lisa M. Boyle  
Sr. Regulatory Affairs Specialist

enclosure

# **ATTACHMENT A**

<b>Translations for Cespace<sup>XP</sup> drawings</b>	
<b>German</b>	<b>English</b>
Röntgenmarker Ø0,91 Drahtlänge angepasst	X-ray marker Ø0,91 wire length adapted
Beschichtung: Plasmapore XP (Spezifikation nach QSV 1054086)	Coating: Plasmapore XP (specifications acc. to QSV 1054086)
Artikel	catalogue number
keine Beschichtung	no coating
Maße gelten im unbeschichteten Zustand	dimensions valid in uncoated condition
Prüfmerkmale	inspection criteria
Anschlussmaße gelten auch nach Beschichtung	connecting dimensions valid also after coating
schutzvermerk nach	protective note

Title Box on Drawings

(b) (4)



## **ATTACHMENT B**

## CeSpace PEEK

### Surgical Technique

[Cover picture from CeSpace PEEK Reference Brochure DOC841 and surgical technique illustration]

## Table of Contents

System Overview.....	3
Indications and Contraindications .....	4
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1. Patient Positioning and Exposure .....	6
2. Preparation / Discectomy .....	6
3. Implant Sizing .....	8
4. Implant Preparation and Insertion.....	9
5. Verification of Final Implant Placement.....	12
6. Implant Removal.....	14
Implant Options.....	15

## System Overview

The CeSpace PEEK Interbody System includes a comprehensive line of implants made of radiolucent PEEK-OPTIMA®\* and high-quality, easy-to-use instrumentation for ACDF (Anterior Cervical Disectomy Fusion) procedures.

### Implant Overview

- Radiolucent for better visualization with no artifact
- Provides strength and dimensional stability
- Similar to bone modulus
- Individually sterile packed

### Features and Benefits

- Tantalum rod markers improve fluoroscopic placement and post-operative examination
- Anatomically shaped to provide better surface area coverage of endplates
- Large interior graft space optimizes bony integration
- Superior and inferior ridges prevents implant migration
- Easy-to-use, color-coded trial system
- Non-threading inserter for easy implant loading and release
- Complete set of rasps included for endplate preparation

['glamour shot' of CeSpace implant]

### Materials:

(b)(4)



## Indications and Contraindications

### Indications for Use

- Intended as an Intervertebral body fusion device designed for use with autogenous bone graft.
- Intended for spinal fusion procedures at one level in the cervical spine from C3-C7.
- Intended for use in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- Intended for use with supplemental spinal fixation systems such as the Aesculap S4 System.
- Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

### Contraindications

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the PEEK devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

### WARNINGS

Implants supplied in sterile condition must not be resterilized or reused under any circumstances. Danger to the patient and possible loss of implant functionality due to resterilization!

### WARNINGS

Increased risk of migration due to over-preparation of the vertebral body endplates! When preparing the implant bed, make certain that the base and cover plates of the adjacent vertebral bodies are not weakened.

### WARNINGS

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union) fracture of the vertebra, neurological injury, and vascular or visceral injury

### CAUTION

Damage to the implant thread!

- Keep to the thread axis when screwing the implant onto the insertion instrument.
- Screw in the implant as far as it will go so that the dihedral of the instrument rests in the groove on the implant.

**CAUTION**

Based upon dynamic testing results physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the CeSpace implant when used as an intervertebral body fusion device.

**RISKS**

The surgical intervention involves the following potential risks:

- Neurological complications caused by over distraction or trauma of the nerve roots or dura
- Loss of intervertebral disk height due to removal of healthy bone material.

Complications that can generally occur in connection with intervertebral surgery:

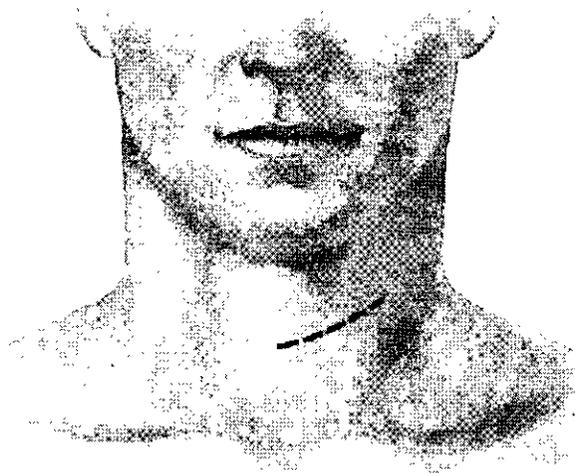
- Pseudarthrosis
- Incorrect implant position
- Spondylolisthesis
- Loss of fixation; dislocation or migration

## Surgical Technique

### 1. Patient Positioning and Exposure

Anterior access will be required for the insertion of the CeSpace PEEK implant. As with any procedure, it is important to understand the lordotic angle of disc spaces and the surrounding anatomy in order to plan for anterior surgery. Pre-operative radiographs should be taken to measure disc heights and the required implant range. Patient positioning and exposure of the anterior cervical spine is performed in accordance with the standard anterior cervical surgical technique.

- Place the patient in the supine position.
- Utilize the standard anterior approach to the cervical spine. (Fig. 1)
- Provide the level of exposure to the implantation site that the surgeon deems necessary to perform the surgery. A cervical retraction system, such as Aesculap's Caspar Cervical Retractor System, can be used to provide adequate visualization to the front of the cervical spine.



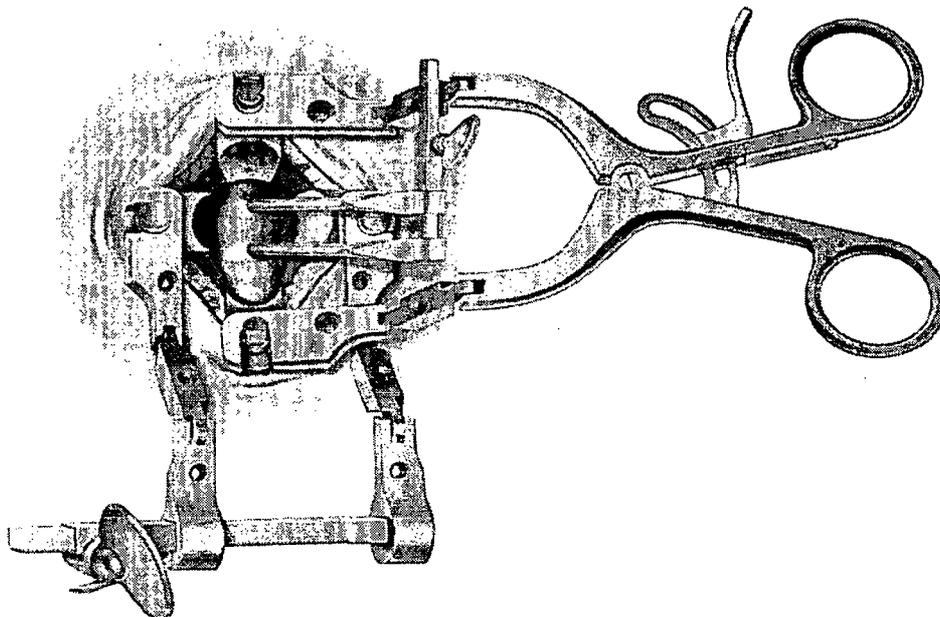
[Figure 1 - Surgical Approach – Demarcation of incision on patient's neck]

### 2. Preparation / Discectomy

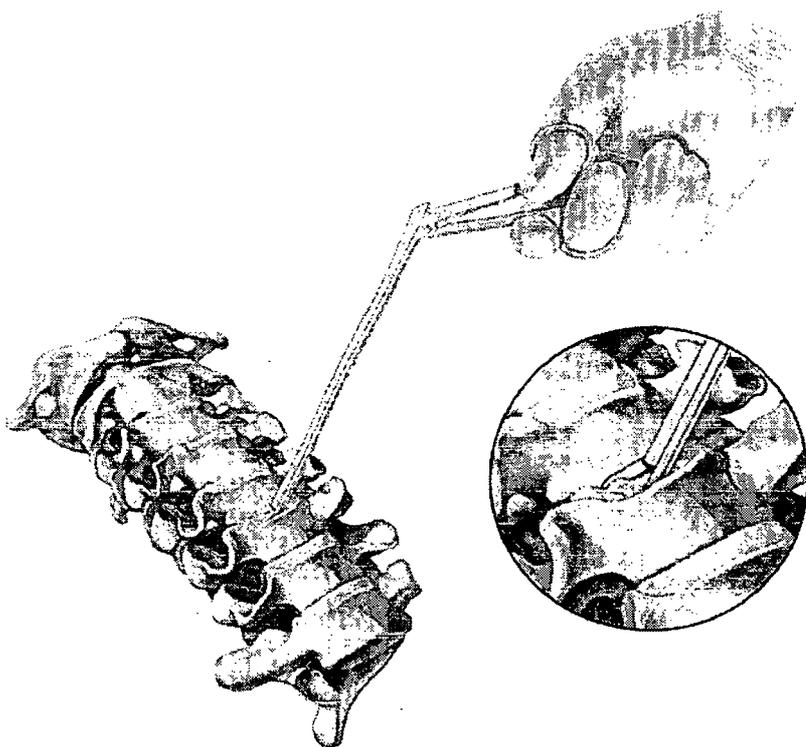
Prepare the intervertebral space by utilizing anterior discectomy instruments that the surgeon feels are necessary to properly prepare the disc space and vertebral endplates.

- A cervical distraction system, such as Aesculap's Caspar Cervical Distraction System, can be used to gradually achieve the desired working height. (Fig. 2)
- Perform a thorough discectomy. (Fig. 3)
- Ensure adequate neural decompression has been established.
- Prepare the endplates to receive the CeSpace PEEK implant. (Fig. 4)

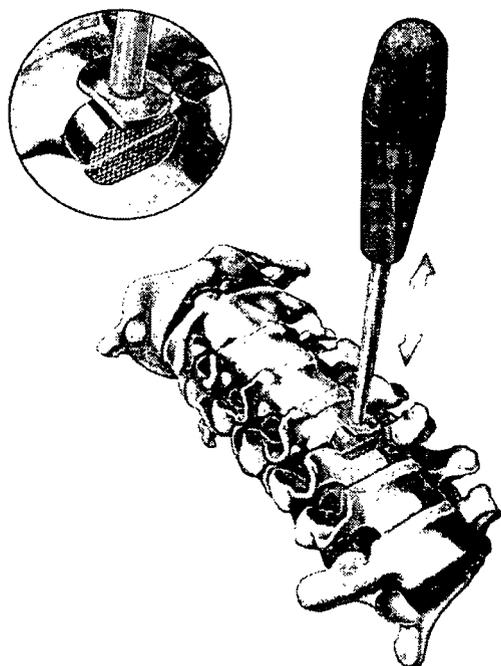
**Note:** Excessive removal of the endplates may weaken the construct and cause subsidence of the implant.



[Figure 2 - Surgical Preparation – Anterior surgical view of the exposure and placement of Aesculap's CCR with distraction pins]



[Figure 3 - Discectomy – C5-6 discectomy performed on oblique view of the cervical spine]



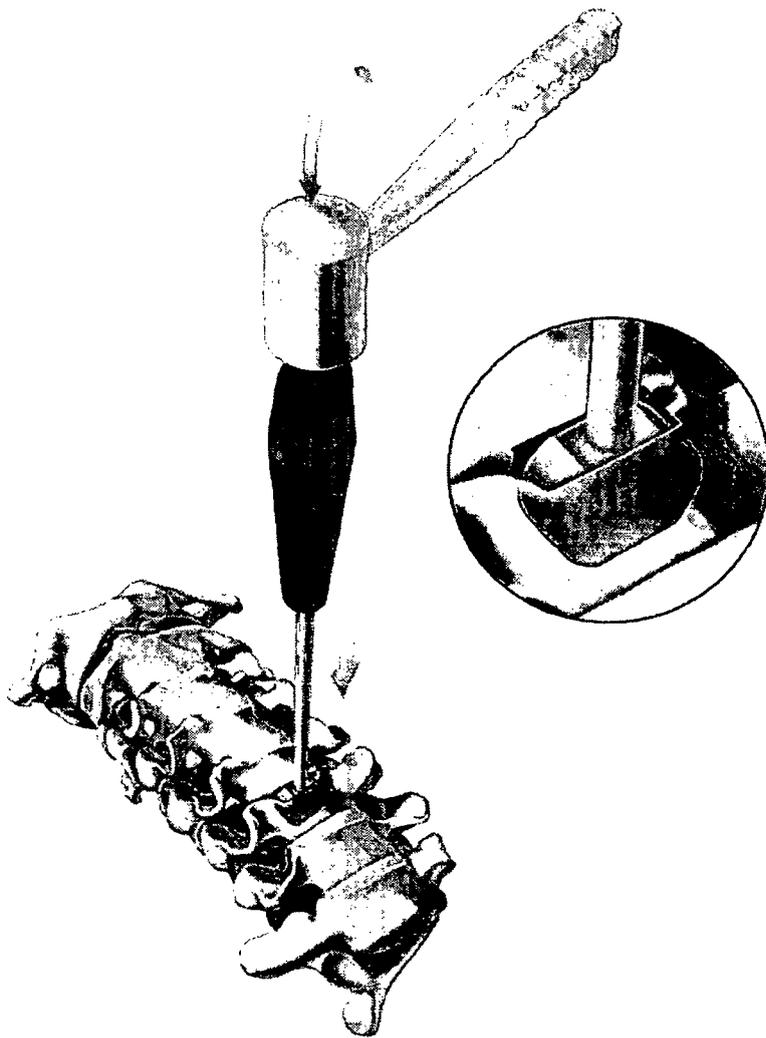
[Figure 4 - Endplate Preparation – Endplates rasped down to bleeding bone to receive the interbody fusion graft]

### 3. Implant Sizing

Proper implant size can be established using the trial spacers while the interspace is distracted. Trial implants are available in two footprint sizes, two lordotic angles, and eight heights. Each trial implant is color-coded by footprint size and labeled with the corresponding footprint, height, and lordotic angle. (See page \_\_\_?\_\_\_ for available sizes.)

- Select an appropriate sized trial implant based on patient anatomy and pre-operative radiographic analysis.
- Utilize the cottle mallet to gently advance the trial into the disc space. (Fig. 5)
- Manipulate the trail implant as needed to attain the desired position.
- Continue to evaluate trial implants until a tight fit is achieved.
- Assess the final implant fit and position with intraoperative AP and lateral fluoroscopy.

**Note:** A properly chosen implant will ensure disc height is maintained and implant migration is minimized.



[Figure 5 - Insertion of Trial Spacer – Trial spacer is inserted horizontally and into the intervertebral space]

#### 4. Implant Preparation and Insertion

- Select the implant that corresponds to the final trial implant size evaluated.

**Note:** The dimensions of the trial implants were designed to match the CeSpace PEEK implants (footprint, height, and lordotic angle).

##### Implant Preparation

- Attach and secure the selected CeSpace PEEK implant to the distal end of the insertion instrument.
  - Insert the inner shaft (FJ497R or FJ415R) into the insertion instrument handle and secure.

**Note:** The insertion instrument consists of a handle plus an inner shaft with a safety stop (FJ497R) or alternatively without a safety stop (FJ415R). It is recommended that the safety stop is utilized to ensure that the implant is seated 1 to 2mm beyond the anterior border of the vertebral body.

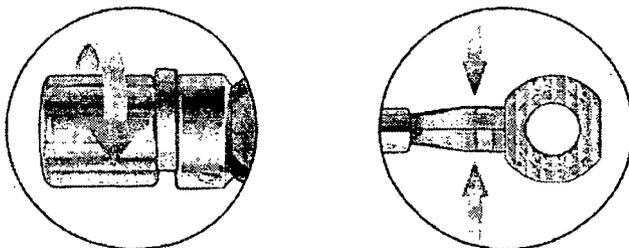
- The handle of the insertion instrument is labeled with the word "Cranial" for orientation purposes during implant insertion. Orient the insertion instrument in the Cranial position and align the distal end with the bilateral holes of the selected CeSpace PEEK implant. (Fig. 6)

**Note:** Laser markings on the insertion instrument indicate the cranial and caudal side of the instrument. In addition, each CeSpace PEEK Implant has an arrow to denote its cranial orientation.

- Attach and secure the selected implant to the distal end of the insertion instrument by turning the proximal knob in a clockwise direction. (Fig. 7)
- Fill the implant with autograft material by utilizing the packing block and tamp. (Fig. 8)
  - Place the implant into the corresponding footprint space of the packing block.
  - Fill the implant with autograft material.
  - Use the tamp to firmly pack autograft material into the implant.

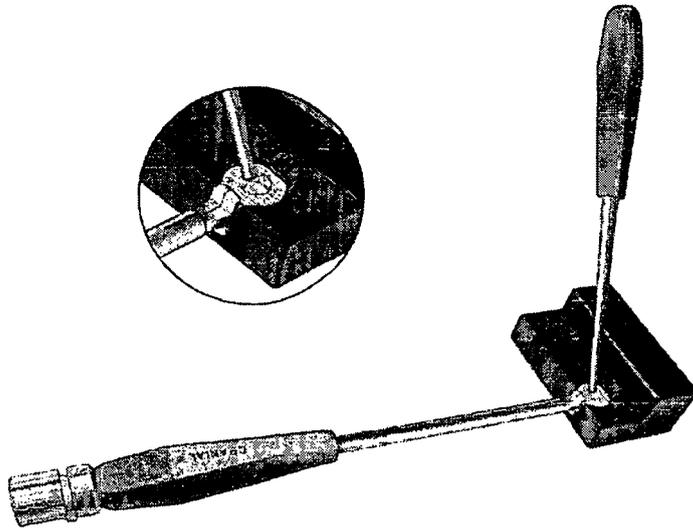


**Note:** The illustration above shows this step with an uncoated CeSpace implant.  
[Figure 6 - Selection of Implant – After the trial implants are inserted, the true implant is selected, handled in a sterile manner and positioned for attachment to the insertion instrument]



**Note:** The illustration above shows this step with an uncoated CeSpace implant.

[Figure 7 - Implant and Inserter – The implant is attached to the insertion instrument, with the upper knob enlarged to detail tightening, and the safety stop enlarged to ensure the implant is seated 1 to 2 mm beyond the anterior border of the vertebral body]



Note: The illustration above shows this step with an uncoated CeSpace implant.

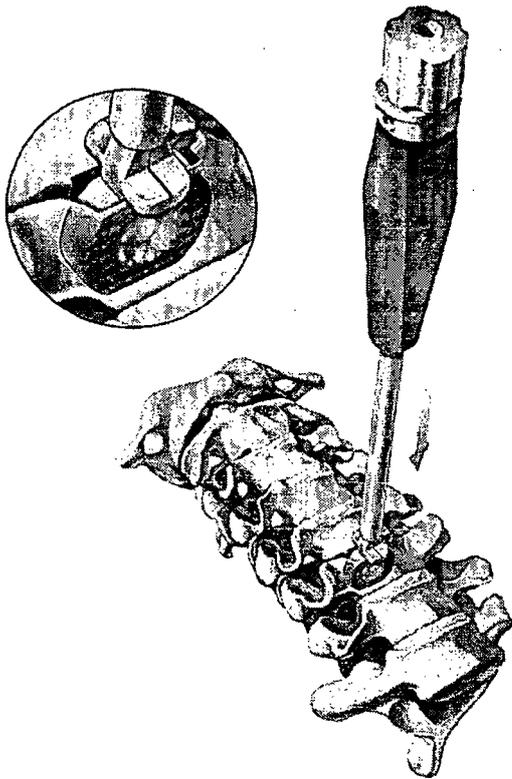
[Figure 8 - Preparation of Implant – The implant is filled with bone or bone substitute by using the packing block]

#### Implant Insertion

- Ensure that the insertion instrument is oriented in the Cranial position.
- Introduce the implant into the disc space. The implant should be inserted centrally in AP and with a distance of approximately 1-2 mm to both the anterior and posterior rim. (Fig. 9)

**Caution:** It is important to consider the midline and neutral alignment while implanting this device to avoid placing neural elements at risk.

**Note:** If using the inserter with safety stop (FJ497R), a positive stop at the end of the insertion sleeve ensures that the graft is positioned within the vertebral space, and helps prevent over insertion and spinal canal compromise.



Note: The illustration above shows this step with an uncoated CeSpace implant.

[Figure 9 - Insertion of Implant into Disc Space – The implant is countersunk horizontally]

## 5. Verification of Final Implant Placement

- Obtain AP fluoroscopic image to confirm midline placement of the device.
- Obtain lateral fluoroscopic images to confirm that the anterior edge of the implant is seated 1 to 2 mm beyond the anterior border of the vertebral body.

Note: It is recommended to confirm implant position prior to removing the insertion instrument.

- Observe the X-Ray markers in both the AP and lateral views to ensure that the implant is not rotated within the disc space.
- Manipulate the implant as needed by gently tapping the impactor with the mallet.
- Relax the Caspar Distractor.

Note: Relaxing the Caspar Distractor places the implant in compression. This allows the grooves on the superior and inferior surfaces of the CeSpace PEEK implant to come in contact with the vertebral body endplates, thereby producing a more secure fit within the intervertebral disc space.

- Check whether the implant is stable and securely positioned.

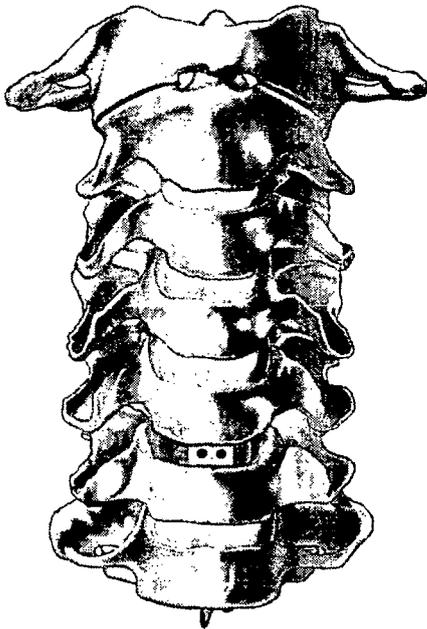
**Caution:** If the implant can be moved slightly in the intervertebral space, there is a risk of dislocation and the implant should be replaced with the next largest size in height.

- Obtain additional AP and lateral fluoroscopic images to document midline placement and neutral alignment.
- The final AP and lateral images should reflect neutral alignment of the CeSpace PEEK implant. (Fig. 10 & Fig. 11)

**Note:** The green lines in Figures 10 & 11 represent the location of the implant X-Ray markers in both the AP and lateral views.

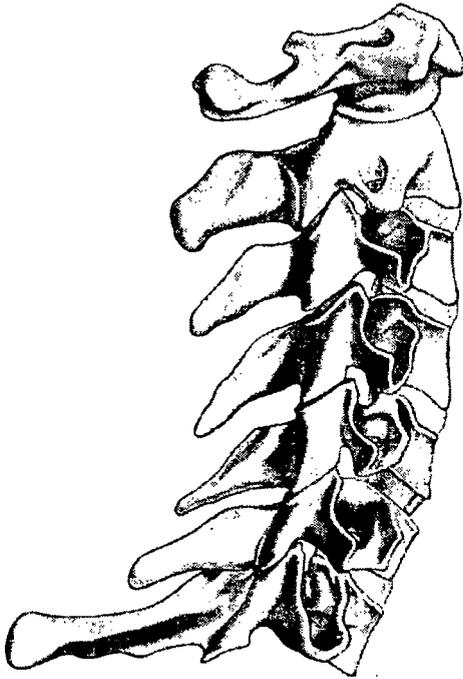
- Once satisfied with the implant location and fit, remove the insertion instrument.

**Note:** Additional stabilization utilizing internal fixation such as the ABC Anterior Cervical Plate is required when using the CeSpace PEEK Interbody System.



**Note:** The illustration above shows this step with an uncoated CeSpace implant.

[Figure 10 - AP view of the complete construct with radiopaque markers visible]



Note: The illustration above shows this step with an uncoated CeSpace implant.

[Figure 11 – Lateral view of the complete construct with radiopaque markers visible]

## 6. Implant Removal

- Insert the inner revision shaft (FJ499R) into the insertion instrument handle and secure.
- Guide and attach the distal end of the insertion instrument to the implant by turning the proximal knob in a clockwise direction.
- Apply an extraction force to the implant insertion instrument with inner revision shaft to remove the implant from the disc space.

## Implant Options

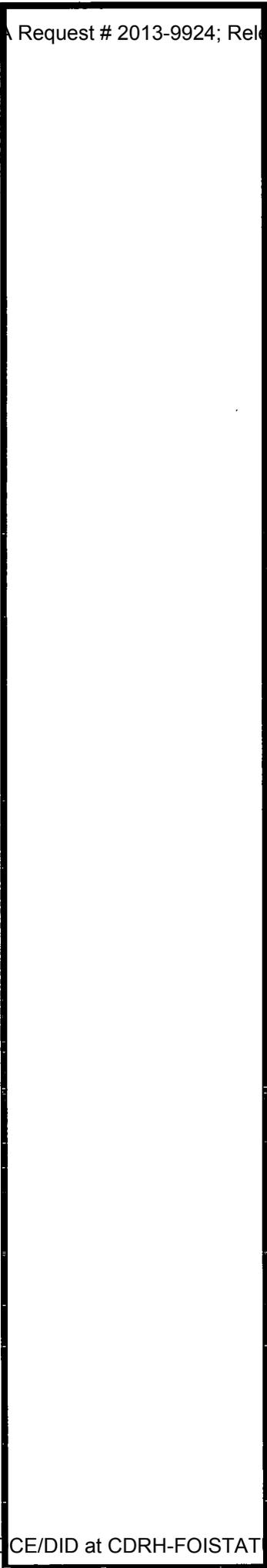
[Insert tables from excel spreadsheet 'CeSpace PEEK Surgical Technique Excel Tables' from tab 'Implant Overview']

[Insert pictures from page 3 of CeSpace PEEK Brochure DOC841 with the following edits:

Replace 'Diameter' with 'Length'

Replace 'Depth' with 'Width'

Add 'Lordosis' in front of Angle]



## **Aesculap CeSpace PEEK Spinal Implant System: Instructions for Use**

### **Indications for use:**

#### *When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

#### *When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

### **Materials**

(b) (4)



### **General Surgical Indications**

Surgically installed implants serve to support normal healing processes. They should neither replace normal structures of the body nor permanently bear the loads occurring in the case of incomplete healing.

### **Contraindications**

The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the PEEK devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses

- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

### **Risks**

The surgical intervention involves the following potential risks:

- Neurological complications caused by over distraction or trauma of the nerve roots or dura
- Loss of intervertebral disk height due to removal of healthy bone material

Complications that can generally occur in connection with intervertebral surgery:

- Pseudarthrosis
- Incorrect implant position
- Spondylolisthesis
- Loss of fixation; dislocation or migration

### **Side-effects and adverse interactions**

None known.

### **Safety notes**

- It is the operating surgeon's responsibility to ensure that the surgical procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present documentation.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be thoroughly familiar with bone anatomy, including the pathways of nerves, blood vessels, muscles and tendons.
- Aesculap is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- The instructions for use of the individual Aesculap implant components must be observed.
- Do not use damaged or surgically excised components under any circumstances.
- Implants that have already been used must not be reused.
- Delayed healing can result in implant rupture due to material fatigue.
- The implant components are supplied with their article numbers, the name of the implant, as well as the batch number and serial number (if applicable) which should be documented in all patient records.
- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed.

### **Sterility**

- The implant components come individually packed in protective packaging that is labeled according to its contents.
- The implant components have been sterilized by irradiation (min. dose 25 kGy).
- Store implant components in their original packaging. Remove them from their original protective packaging only just prior to application.
- Prior to use, check the product expiry date and verify the integrity of the sterile packaging. Do not use implant components that are past their expiry date or if the package is damaged.

### **Application**

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:

- Selection of the implant components and their dimensions
- Positioning of the implant components in the bone
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:

- All requisite implant components are ready to hand
- Operating conditions are highly aseptic
- The implantation instruments, including the special Aesculap implant system instruments, are complete and in working condition.
- The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready to hand.
- The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

The intervention has been explained to the patient, whose consent concerning the following information has been documented:

- In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
- The life-span of the implant depends on the patient's body weight.
- Corrective surgery may become necessary if the implant loosens.
- The patient must undergo regular check-ups of the implant components, performed by a physician.

### **Implanting the PEEK devices**

- Select the appropriate PEEK implant size and shape according to the indication, the preoperative planning, and the bone situation found intraoperatively.
- Correctly apply the preparation instruments (rasps, curettes and chisels) for preparing the implant bed, as well as the implantation instrument.
- Apply appropriate care when inserting the implant.
- Check implant height and/or angle using the trial implants.

Further information on B. Braun/Aesculap implant systems is always available from B. Braun/Aesculap or the relevant B. Braun/Aesculap agency.

### **WARNING**

Implants supplied in sterile condition must not be resterilized or reused under any circumstances. Danger to the patient and possible loss of implant functionality due to resterilization!

### **WARNING**

Increased risk of migration due to over-preparation of the vertebral body endplates!  
When preparing the implant bed, make certain that the base and cover plates of the adjacent vertebral bodies are not weakened.

**WARNINGS**

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union) fracture of the vertebra, neurological injury, and vascular or visceral injury.

**CAUTION**

Damage to the implant thread!

- Keep to the thread axis when screwing the implant onto the insertion instrument.
- Screw in the implant as far as it will go so that the dihedron of the instrument rests in the groove on the implant.

**CAUTION**

Based upon dynamic testing results physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the CeSpace implant when used as an intervertebral body fusion device.

**Distributed in the U.S. by:**

Aesculap Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034

Phone: 800-234-9179

**Caution: United States (Federal) law restricts these devices to sale by or on the order of a physician.**

SOP-AIS-5000648 Rev. XXXX

*Contains Nonbinding Recommendations*

## Appendix – Acceptance Checklists

### Acceptance Checklist for Traditional 510(k)s

**(should be completed within 15 days of DCC receipt)**

*The following information is not intended to serve as a comprehensive review.*

510(k) Number: K123909 Date Received by DCC: 12/19/2012

Lead Reviewer Name: Katherine Kavlock Branch: ASDB Division: DOD Office: ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	Yes	No
<p><b>1. Is the product a device (per section 201(h) of the FD&amp;C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</b></p> <p>If it appears not to be a device (per section 201(h) of the FD&amp;C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p>	X	
Comments:		
<p><b>2. Is the application with the appropriate Center?</b></p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p>	X	
Comments:		

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<p><b>3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</b></p> <p>a) <b>Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</b></p> <p>b) <b>Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?</b></p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide summary of Jurisdictional Officer's/Liaison's determination.</i></p> <p>If the answer to either question above is no, mark "No." If there was no RFD, skip this question.</p>		
<p><b>Comments:</b></p>		
<p><b>4. Is this device type eligible for a 510(k) submission?</b></p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p>	X	
<p><b>Comments:</b></p>		
<p><b>5. Is there a pending PMA for the same device with the same indications for use?</b></p> <p>If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p>		X
<p><b>Comments:</b></p>		
<p><b>6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</b></p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at <a href="http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm">http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm</a>.</p>		X

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter. If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

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If the answer to 4 is “No”, the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 5 is “Yes,” then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 6 is “Yes,” then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO’s recommendation/action.

<b><u>Organizational Elements</u></b>		
<i>Failure to include these items alone generally should not result in an RTA designation</i>		
	Yes	No
a. Submission contains Table of Contents	X	<input type="checkbox"/>
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	<input type="checkbox"/>
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	X	<input type="checkbox"/>
d. Type of 510(k) is identified– traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i>	X	<input type="checkbox"/>
Comments:		

<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>				
Submission should be designated RTA if not addressed				
Check “Yes” if item is present, “N/A” if it is not needed and “No” if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> <li>Any “No” answer will result in a “Refuse to Accept” decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
<b>A.</b>	<b>Administrative</b>			
	1. All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	<input type="checkbox"/>		X
	Comments: The engineering drawings (pages 016-019) were provided in a language other than English and a translation has not been provided.			
	2. Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X		<input type="checkbox"/>

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Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
	a.	Device trade name or proprietary name	X		<input type="checkbox"/>
	b.	Device common name	X		<input type="checkbox"/>
	c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X		<input type="checkbox"/>
		Comments:			
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	X		<input type="checkbox"/>
		Comments:			
	4.	Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.</i>	X		<input type="checkbox"/>
	a.	Summary contains all elements per 21 CFR 807.92 <i>See also 510(k) Summary Checklist</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
	b.	Statement contains all elements per 21 CFR 807.93	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Comments:			
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).</i>	X		<input type="checkbox"/>

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Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>	Yes	N/A	No
	Comments:			
6.	Submission contains Class III Summary and Certification <i>See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
	Comments:			
7.	Submission contains clinical data <i>Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	<input type="checkbox"/>	X	
	a. Submission includes completed Financial Certification ( <u>FDA Form 3454</u> ) or Disclosure ( <u>FDA Form 3455</u> ) information for each covered clinical study included in the submission. <i>Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the <u>Guidance for Industry- Financial Disclosures by Clinical Investigators</u></i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank ( <u>FDA Form 3674</u> ) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. <i>Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in <u>Title VIII of FDAAA, Sec. 801(j)</u></i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
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 ( <u>FDA Form 3654</u> ) <i>There should be a completed form for each referenced national or international standard.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>

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Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
		Select "N/A" only if submission does not reference any standards.			
		Comments:			
	9.	<p>The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.</p> <p><i>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 (prior related submissions section) of the CDRH Coversheet form (Form 3514) 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.</i></p>	X		<input type="checkbox"/>
	a.	<p>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.</p> <p><i>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 a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "<u>Medical Devices: The Pre-Submission Program and Meetings with FDA Staff.</u>" (<a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm3">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm3</a>)</i></p>	<input type="checkbox"/>	X	<input type="checkbox"/>

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<b><u>Elements of a Complete Submission (RTA Items)</u></b> <b><u>(21 CFR 807.87 unless otherwise indicated)</u></b>								
Submission should be designated RTA if not addressed								
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>								
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>				Yes	N/A	No	
			<p><a href="#">10375.htm</a>). Once finalized, this guidance will represent the Agency's current thinking on this topic.  <i>Select "N/A" if the submitter states there were no prior submissions in criterion above.</i></p>					
	Comments:							
<b>B.</b>	<b>Device Description</b>							
	10.	a.	<p>If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.  <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i></p>			<input type="checkbox"/>	X	<input type="checkbox"/>
		b.	<p>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.  <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i></p>			X	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:							

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Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
	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:			
	a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	X		<input type="checkbox"/>
	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.	X		<input type="checkbox"/>
	c.	A list and description of each device for which clearance is requested. <i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
		Comments:			
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.  <i>In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.</i>  <i>Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
		Comments: The submission contains representative engineering drawings; however, they are			

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Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
		illegible as they are written in German. See comments for question number 1 above.			
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>		<input type="checkbox"/>	
	a.	Submission includes a list of all components and accessories to be marketed with the subject device.	X		<input type="checkbox"/>
	b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. <i>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.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
	c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>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.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
		Comments:			
<b>C.</b>	<b>Substantial Equivalence Discussion</b>				
	14.	Submitter has identified a predicate(s) device	X		<input type="checkbox"/>
	a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is</i>	X		<input type="checkbox"/>

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Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
		<i>available online</i> <a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm</a>			
	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.	X		<input type="checkbox"/>
		Comments:			
	15.	Submission includes a comparison of the following for the predicate(s) and subject device			
	a.	Indications for use	X		<input type="checkbox"/>
	b.	Technology, including features, materials, and principles of operation	X		<input type="checkbox"/>
		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 (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) <i>If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive</i>	X	<input type="checkbox"/>	<input type="checkbox"/>

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Submission should be designated RTA if not addressed				
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>				
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>	Yes	N/A	No
	<i>review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.</i>			
	Comments:			
<b>D.</b>	<b>Proposed Labeling (see also 21 CFR part 801)</b> <i>If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.</i>		<input type="checkbox"/>	
	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	X		<input type="checkbox"/>
	a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	X		<input type="checkbox"/>
	b. Submission includes directions for use that <ul style="list-style-type: none"> <li>include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND</li> <li>Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D</li> </ul>	<input type="checkbox"/>		X
	Comments: The directions for use (surgical technique manual) include only contraindications and not all relevant hazards, warning, and precautions.			
	18. If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also	<input type="checkbox"/>	<input type="checkbox"/>	X

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Submission should be designated RTA if not addressed						
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>						
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			Yes	N/A	No
	<u>Alternative to Certain Prescription Device Labeling Requirements</u> <i>Select "N/A" if not indicated for prescription use.</i>					
	Comments: The sample package label and package insert do not contain the prescription use statement or the Rx only symbol.					
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X		<input type="checkbox"/>
		b.	Labeling includes device common or usual name (21 CFR 801.61) <i>Select "N/A" if device is for prescription use only.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
	Comments:					
	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 requirement. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
		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. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a</i>	<input type="checkbox"/>	X	<input type="checkbox"/>

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Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
				Yes	N/A	No
			<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
			<i>device-specific guidance have been addressed should be assessed during the substantive review.</i>			
		c.	<p>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 at least an equivalent assurance of safety and effectiveness.</p> <p><i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	X
			<p>Comments: Special Controls Guidance: Intervertebral Body Fusion Device (Section 13) recommends the following be included in the labeling:</p> <ul style="list-style-type: none"> <li>Brief device description identifying the component materials (no mention of Plasmapore/titanium coating)</li> <li>Labeling should include <b>warnings</b> describing the risks and potential adverse outcomes. for example:</li> </ul> <p style="text-align: center;"><i>Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral injury.</i></p> <p>Special Controls Guidance: Intervertebral Body Fusion Device (Section 13) recommends the following be included in the Instructions for Use/Surgical Technique Manual:</p> <ul style="list-style-type: none"> <li>Supporting magnified sketches of the major steps</li> <li>Removal or revision procedures</li> </ul>			

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Submission should be designated RTA if not addressed					
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>					
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>	Yes	N/A	No	
21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>	
<b>E.</b>	<b>Sterilization</b> <i>If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>		<input type="checkbox"/>		
	Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i> X provided sterile <input type="checkbox"/> provided non-sterile but sterilized by the end user <input type="checkbox"/> non-sterile when used  This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.</i> <i>If information regarding the sterility status of the device is not provided, select "No."</i>			<input type="checkbox"/>	
	Comments:				
22.	Assessment of the need for sterilization information				
	a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X	<input type="checkbox"/>	<input type="checkbox"/>
	b.	Identification of device, and/or accessories, and/or components that are end user sterilized	<input type="checkbox"/>	<input type="checkbox"/>	X
	c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	<input type="checkbox"/>	<input type="checkbox"/>	X

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
		Comments: No cleaning instructions or sterilization parameters have been included for reusable, system-specific instruments.			
	23.	If the device, and/or accessory, and/or a component is provided sterile: <i>Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.</i>		<input type="checkbox"/>	
	a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		<input type="checkbox"/>
	b.	A description of 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. <i>Note, the sterilization validation report is not required.</i>	X		<input type="checkbox"/>
	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. <i>Select "N/A" if not sterilized using chemical sterilants.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
	d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X		<input type="checkbox"/>
	e.	Sterility Assurance Level (SAL) stated	X		<input type="checkbox"/>
		Comments:			
	24.	If the device, and/or accessory, and/or a component is end user sterilized: <i>Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.</i>		<input type="checkbox"/>	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
			Yes	N/A	No	
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>				
	a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	<input type="checkbox"/>		X	
	b.	A description of 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. <i>Note, the sterilization validation is not required.</i>	<input type="checkbox"/>		X	
	c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	<input type="checkbox"/>		X	
	d.	Submission includes sterilization instructions for end user	<input type="checkbox"/>		X	
		Comments: No cleaning instructions or sterilization parameters have been included for reusable, system-specific instruments.				
	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. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
		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.	<input type="checkbox"/>	X	<input type="checkbox"/>

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
		<i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>			
	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. <i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
		Comments:			
<b>F.</b>	<b>Shelf Life</b>				
	26.	Proposed shelf life/ expiration date stated <i>Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
		Comments:			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
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.  <i>Select "N/A" if the device is not provided sterile.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
	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 safety or effectiveness.	<input type="checkbox"/>		X
	Comments: The sponsor has not included a rationale for why the storage conditions are not expected to affect device safety or effectiveness.			
<b>G.</b>	<b>Biocompatibility</b> <i>If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.</i>		<input type="checkbox"/>	
	Submission states that there: <i>(one of the below must be checked)</i> X are <input type="checkbox"/> 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. <i>If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."</i>			<input type="checkbox"/>
	Comments:			

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>	Yes	N/A	No
29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X		<input type="checkbox"/>
	Comments:			
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	X		<input type="checkbox"/>
	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).	X		<input type="checkbox"/>
	Comments:			
<b>H.</b>	<b>Software</b>			
	Submission states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does <input checked="" type="checkbox"/> does not contain software/firmware.  This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."</i>			<input type="checkbox"/>

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Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
	Comments:			
	32. Submission includes a statement of software level of concern and rationale for the software level of concern	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
	33. All applicable software documentation provided based on level of concern identified by the submitter, as described in <u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u> , 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).	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
<b>I.</b>	<b>EMC and Electrical Safety</b>			
	Submission states that the device: <i>(one of the below must be checked)</i> <input type="checkbox"/> does X 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. <i>If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."</i>			<input type="checkbox"/>
	Comments:			
	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),	<input type="checkbox"/>		<input type="checkbox"/>

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			
	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).			
	Comments:			
	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).	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
<b>J.</b>	<b>Performance Data – General</b> <i>If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.</i>		<input type="checkbox"/>	
	Comments:			
	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	X	<input type="checkbox"/>	<input type="checkbox"/>

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		<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>	<b>Yes</b>	<b>N/A</b>	<b>No</b>
		from the test supports a finding of substantial equivalence. <i>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.</i>			
		Comments:			
	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. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
		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 approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
		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	X	<input type="checkbox"/>	<input type="checkbox"/>

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				Yes	N/A	No	
			<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>				
			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. <i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i>				
		Comments:					
	38.	If literature is referenced in the submission, submission includes: <i>Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.</i>				X	
		a.	Legible reprints or a summary of each article	<input type="checkbox"/>		<input type="checkbox"/>	
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	<input type="checkbox"/>		<input type="checkbox"/>	
		Comments:					
	39.	For each completed nonclinical (i.e., animal) study conducted, <i>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,</i>				X	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	<input type="checkbox"/>		<input type="checkbox"/>	
		b.	Submission includes final study report which includes all elements	<input type="checkbox"/>		<input type="checkbox"/>	

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	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>				<b>Yes</b>	<b>N/A</b>	<b>No</b>	
			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 data provided to support a substantial equivalence determination.	<input type="checkbox"/>			<input type="checkbox"/>	
	Comments:							
<b>K.</b>	<b>Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))</b>							
	Submission indicates that device: <i>(one of the below must be checked)</i> <input type="checkbox"/> is <input checked="" type="checkbox"/> is not an in vitro diagnostic device (IVD). <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>							
	Comments:							
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:						
		a.	Precision/reproducibility	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
		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.	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	

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	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>				<b>Yes</b>	<b>N/A</b>	<b>No</b>
	c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	d.	Analytical specificity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Comments:							
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. <i>Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	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 approach. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

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Submission should be designated RTA if not addressed						
<b>Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.</b>						
	<ul style="list-style-type: none"> <li>Any "No" answer will result in a "Refuse to Accept" decision.</li> <li>Each element on the checklist should be addressed within the submission. 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.</li> </ul>			Yes	N/A	No
		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. <i>Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.</i>				
	Comments:					

**Decision:** Accept  Refuse to Accept

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

<b>Digital Signature Concurrence Table</b>	
Reviewer Sign-Off	Katherine D. Kavlock 2013.01.02 14:43:34 -05'00'
Branch Chief Sign-Off	Colin O'Neill 2013.01.02 15:09:16 -05'00'
Division Sign-Off	Erin I. Keith 2013.01.03 11:04:24 -05'00'

Acceptance Checklist for Traditional 510(k)



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

December 19, 2012

AESFULAP IMPLANT SYSTEM, INC.  
3773 CORPORATE PARK WAY  
CENTER VALLEY, PENNSYLVANIA 18034  
ATTN: LISA M. BOYLE

510k Number: K123909

Received: 12/19/2012

Product: AESFULAP CESPAC EX

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

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

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

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

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015  
Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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

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

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

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

Sincerely,

510(k) Staff

**Nichols, Karl \***

---

**From:** Lisa.Boyle@aesculap.com  
**Sent:** Wednesday, December 19, 2012 2:28 PM  
**To:** Nichols, Karl \*  
**Subject:** AUTO: Lisa Boyle (returning 01/03/2013)

I am out of the office until 01/03/2013.

I am currently out of the office. If you need immediate regulatory assistance, please contact Jody Reinert at X5063

For all customs inquires, please contact Denise Adams at (610) 984-9076 or via e-mail at [denise.adams@aesculap.com](mailto:denise.adams@aesculap.com).

Happy Holidays!!

Thanks,  
Lisa

Note: This is an automated response to your message "K123909- Ack Letter" sent on 12/19/2012 02:24:34 PM.

This is the only notification you will receive while this person is away.

\*\*\*\*\*  
The information contained in this communication is confidential, may be attorney-client privileged, may constitute inside information, and is intended only for the use of the addressee. It is the property of the company of the sender of this e-mail. Unauthorized use, disclosure, or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify us immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.  
\*\*\*\*\*

## Attachment

**Attachment for Submission Number(s):**

**K123909**

**The list below identifies the reason(s) why your eCopy failed FDA's eCopy validation process.  
All of these items need to be addressed or your eCopy will not pass the validation process.**

- 1. The following PDF file(s) have an invalid naming convention (e.g., numbering scheme incorrect, no underscore between number and descriptive name, descriptive name includes prohibited special characteristics):**

Traditional 510(k) CeSpace XP.pdf

Form Approved OMB No. 0910-5111 Expiration Date February 28, 2013 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover-sheet.html">http://www.fda.gov/oc/mdufma/cover-sheet.html</a>		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  AESCULAP IMPLANT SYSTEMS INC 3773 Corporate Parkway Center Valley PA 18034 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b) (4)	2. CONTACT NAME Lisa Boyle  2.1 E-MAIL ADDRESS lisa.boyle@aesculap.com  2.2 TELEPHONE NUMBER (include Area code) 610-984-9274  2.3 FACSIMILE (FAX) NUMBER (Include Area code) 610-791-6882	
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: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER  3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business  4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed: see <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
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)		10-Dec-2012

"Close Window" Print Cover sheet

11/6

# CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission: 12/18-2012  
 User Fee Payment ID Number: (b) (4)  
 FDA Submission Document Number (if known):

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

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

## SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Aesculap Implant Systems, Inc.		Establishment Registration Number (if known) 3005673311	
Division Name (if applicable)		Phone Number (including area code) ( 610 ) 984-9274	
Street Address 3773 Corporate Parkway		FAX Number (including area code) ( 610 ) 791-6882	
City Center Valley	State / Province PA	ZIP/Postal Code 18034	Country USA
Contact Name Lisa M. Boyle			
Contact Title Regulatory Affairs Specialist		Contact E-mail Address Lisa.boyle@aesculap.com	

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

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

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager			
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment			
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

SECTION D2			REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing			
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final					
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

SECTION D3			REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology			
<input type="checkbox"/> Other Reason ( <i>specify</i> ):					

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed

1	MAX	2		3		4	
		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K083311	1	Aesculap CeSpace PEEK Intervertebral Fusion Device	1	Aesculap® Implant Systems
2	K111122	2	Aesculap SIBD XP Spinal System	2	Aesculap® Implant Systems
3		3		3	
4		4		4	
5					
6		6		6	

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification

Adjustable vertebral body replacement device

	Trade or Proprietary or Model Name for This Device		Model Number
1	Aesculap CeSpace XP	1	various
2		2	
3		3	
4		4	

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

1	K083311	2	K111122	3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

- Laboratory Testing
- Animal Trials
- Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code ODP	C.F.R. Section (if applicable) 888.3080	Device Class
Classification Panel Orthopedics		<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 9610612		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Aesculap AG			Establishment Registration Number 9610612		
Division Name (if applicable)			Phone Number (including area code) ( 011-49 ) 7461 95 2625		
Street Address Aesculap Platz			FAX Number (including area code) ( 011-49 ) 74610 95 2177		
City Tuttlingen		State / Province	ZIP/Postal Code	Country Germany	
Contact Name Konrad Kobel		Contact Title Vice President of Regulatory Affairs and Quality Management		Contact E-mail Address	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name (b) (4)			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) (b) (4)		
Street Address (b) (4)			FAX Number (including area code) (b) (4)		
City (b) (4)		State / Province	ZIP/Postal Code (b) (4)	Country (b) (4)	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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	F1854	ASTM	Standard Test Method for stereological evaluation of Porous Coating on Medical Implants		
2	F 2267	ASTM	Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression	04	
3	F 2077	ASTM	Test Methods For Intervertebral Body Fusion Devices	03	
4	F 2026	ASTM	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications		
	F 560	ASTM	Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)		
6	5832-3	ISO	Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium al		1996
7	F1978	ASTM	Standard test method for measuring abrasion resistance of metallic thermal spray coating by using the taber abraser		

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

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

**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	F1160	ASTM	Standard Test method for shear and bending fatigue testing of calcium phosphate and metallic medical and composite calcium phosphate/metallic coatings		
2	F1147	ASTM	Test Method for tension testing of calcium phosphate and metallic coatings		
3	F1044	ASTM	Standard Test Method for shear testing of calcium phosphate coatings and metallic coatings		
4					
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

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

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 <sup>1</sup>

ASTM F1854: STANDARD TEST METHOD FOR STEREOLOGICAL EVALUATION OF POROUS COATINGS ON MEDICAL IMPLANTS

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 8-192

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> 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 the standard? .....         
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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement, April 28, 1994

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> 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>

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

Department of Health and Human Services  
Food and Drug Administration

**STANDARDS DATA REPORT FOR 510(K)**

*(To be filled in by applicant)*

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F-2077: Test Methods for Intervertebral Body Fusion Devices

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA<sup>2</sup>? .....      

FDA Recognition number<sup>3</sup> ..... # 11-816

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report<sup>4</sup> 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 the standard? .....         
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)<sup>5</sup>? .....      

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<sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: Special Controls Guidance Document: Intervertebral Body Fusion Device, June 12, 2007

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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 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.

<sup>5</sup> 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>

<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

Department of Health and Human Services  
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F-2267: Standard Test Method for Measuring Load Induced Subsidence of an IBFC under Static Axial Compression

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 11-185

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> 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 the standard? .....         
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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: Guidance for Industry and FDA Staff Spinal Systems (510(k)'s, May 3, 2004

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> 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>

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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 <sup>1</sup>

ASTM F1147: TEST METHOD FOR TENSION TESTING OF CALCIUM PHOSPHATE AND METALLIC COATINGS

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 8-113

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> 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 the standard? .....         
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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement, April 28, 1994

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt 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 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.

<sup>5</sup> 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>

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F1044: STANDARD TEST METHOD FOR SHEAR TESTING OF CALCIUM PHOSPHATE COATINGS AND METALLIC COATINGS

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 8-112

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> 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 the standard? .....         
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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement, April 28, 1994

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> 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 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.

<sup>5</sup> 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>

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Department of Health and Human Services  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F1160: STANDARD TEST METHOD FOR SHEAR AND BENDING FATIGUE TESTING OF CALCIUM PHOSPHATE AND METALLIC MEDICAL AND COMPOSITE CALCIUM PHOSPHATE/METALLIC COATINGS

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 8-111

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> 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 the standard? .....         
 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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement, April 28, 1994

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

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F1978: STANDARD TEST METHOD FOR MEASURING ABRASION RESISTANCE OF METALLIC THERMAL SPRAY COATINGS BY USING THE TABER ABRASER

**Please answer the following questions**

Yes                      No

Is this standard recognized by FDA <sup>2</sup>? .....                      

FDA Recognition number <sup>3</sup> ..... # 8-142

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....                      

Is a summary report <sup>4</sup> 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 the standard? .....                         
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) <sup>5</sup>? .....                      

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 <sup>6</sup> that is associated with this standard? .....                         
If yes, was the guidance document followed in preparation of this 510k? .....                      

Title of guidance: Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone Or Bone Cement, April 28, 1994

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> 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

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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Department of Health and Human Services  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 5832-3: Implants for Surgery --Metallic Materials--Part 3: Wrought Titanium 6-aluminium 4-vanadium alloy (materials), 2006

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # 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 <sup>4</sup> 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 the standard? .....         
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) <sup>5</sup>? .....      

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....         
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Were there any exclusions from the standard? .....         
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....         
If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

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<sup>5</sup> 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>

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TYPE OF 510(K) SUBMISSION

Traditional                       Special                       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F560: STANDARD SPECIFICATION FOR UNALLOYED TANTALUM FOR SURGICAL IMPLANT APPLICATIONS (UNS R05200, UNS R05400)

**Please answer the following questions**

Yes                      No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes                       No

FDA Recognition number <sup>3</sup> ..... # NA

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes                       No

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....  Yes                       No  
 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? .....  Yes                       No

Does this standard include acceptance criteria? .....  Yes                       No  
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of the standard? .....  Yes                       No  
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....  Yes                       No  
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes                       No

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....  Yes                       No  
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes                       No  
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....  Yes                       No  
 If yes, was the guidance document followed in preparation of this 510k? .....  Yes                       No

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> 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 address of the test laboratory or

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<sup>5</sup> 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>

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**STANDARDS DATA REPORT FOR 510(K)**  
*(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 <sup>1</sup>

ASTM F2026: STANDARD SPECIFICATION FOR POLYETHERETHERKETONE (PEEK) POLYMERS FOR SURGICAL IMPLANT APPLICATIONS, 2008

**Please answer the following questions**

Yes      No

Is this standard recognized by FDA <sup>2</sup>? .....      

FDA Recognition number <sup>3</sup> ..... # NA

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....      

Is a summary report <sup>4</sup> 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 the standard? .....         
 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) <sup>5</sup>? .....      

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 <sup>6</sup> that is associated with this standard? .....         
 If yes, was the guidance document followed in preparation of this 510k? .....      

Title of guidance: \_\_\_\_\_

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

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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 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.

<sup>5</sup> 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>

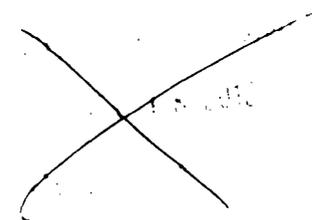
<sup>6</sup> The online search of CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

K18  
K12 3909

December 18, 2012

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center – WO66-0609  
10903n New Hampshire Avenue  
Silver Springs, MD 20993-0002

DEC 19 2012



**Re: Traditional 510(k) Notification – Aesculap® Implant Systems (AIS): CeSpace PEEK Intervertebral Body Fusion System**

Dear Document Control:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 CFR Part 807.87, please find enclosed a Premarket Notification application for a modification to the Aesculap Implant Systems (AIS) CeSpace PEEK Intervertebral Body Fusion System (K083311), a class II product. The modification is for the addition of a Plasmapore® coating to the PEEK device. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft. The devices listed in this submission have not been introduced in any other prior submissions, therefore; FDA has not provided any feedback on the subject devices.

AIS requests that FDA hold as confidential information its intent to market their CeSpace XP Spinal Implant System as we consider this to be confidential commercial information and therefore, exempt from public disclosure, pursuant to the requirements of 21 CFR §807.95(b).

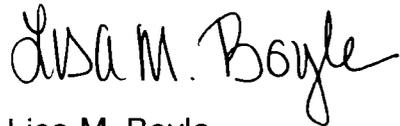
**Design and Use of Device:**

Question	YES	NO
Is the device intended for prescription use [21 CFR 801(d)]?	X	
Is the device intended for over-the-counter use [21 CFR 807(c)]?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

In order to comply with ¶1920, §513 of the Safe Medical Devices Act of 1990, we have provided a 510(k) Summary of Safety and Effectiveness, as well as, a Truthful and Accurate Statement [as required by 21 CFR 807.87(j)] and the Indications for Use statement. The eCopy is an exact duplicate of the paper copy.

Lastly, we ask that notification of clearance be sent to Aesculap® via email at [lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com) and via fax at 610-791-6882.

Sincerely,

A handwritten signature in black ink that reads "Lisa M. Boyle". The signature is written in a cursive, flowing style.

Lisa M. Boyle  
Sr. Regulatory Affairs Specialist

enclosure

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**SECTION I**  
**REQUIRED STATEMENTS**

**INDICATIONS FOR USE STATEMENT**  
**510(k) SUMMARY**  
**TRUTHFUL AND ACCURATE STATEMENT**  
**CLASS III SUMMARY AND CERTIFICATION**  
**FINANCIAL CERTIFICATION AND DISCLOSURE STATEMENT**  
**DECLARATION OF CONFORMITY**

**A. INDICATIONS FOR USE STATEMENT**

**510(k) Number:** \_\_\_\_\_

**Device Name: Aesculap® Implant Systems (AIS) – CeSpace XP Intervertebral Body Fusion System**

**Indications for Use:**

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

Prescription Use \_\_\_\_\_  \_\_\_\_\_ and/or Over-the-Counter Use \_\_\_\_\_

(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

**Aesculap® Implant Systems(AIS) – CeSpace XP Intervertebral Body Fusion System**

December 18, 2012

**COMPANY:** Aesculap® Implant Systems (AIS), LLC.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Lisa M. Boyle, Sr. Regulatory Affairs Specialist  
610-984-9274 (phone)  
610-791-6882 (fax)  
lisa.boyle@aesculap.com

**TRADE NAME:** AIS CeSpace XP Intervertebral Body Fusion System  
**COMMON NAME:** Intervertebral Body Fusion Device  
**CLASSIFICATION NAME:** Orthosis, Spinal Intervertebral Fusion  
**REGULATION NUMBER:** 888.3080  
**PRODUCT CODE:** ODP  
**REVIEW PANEL:** Orthopedics

**INDICATIONS FOR USE**

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

## **DEVICE DESCRIPTION**

The Aesculap CeSpace XP Intervertebral Body Fusion System is a cervical intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of sizes to meet the requirements of the individual patient anatomy. Components are manufactured from PEEK – Optima LT1 (per ASTM F2026) with a titanium layer and a vacuum plasma spray coating (Plasmapore® - per ISO 5832-3). The device will have Tantalum markers per ASTM F-560.

## **TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The components of the CeSpace XP Intervertebral Body Fusion System are offered in the same range of shapes and sizes as the predicate device. The material used for the Aesculap® Implant Systems device is the same as that used to manufacture the predicate devices. The only difference between the predicate device and the subject device is the titanium layer and a vacuum plasma spray coating (Plasmapore®).

## **PERFORMANCE DATA**

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the AIS SIBD XP Spinal System is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic torsion per ASTM F2077
- Static and dynamic axial compression per ASTM F2077
- Shear resistance evaluation
- Subsidence per ASTM F2267

In addition to FDA's Spine Guidance, Aesculap has also completed non-clinical testing recommended in the "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements." The following tests were performed:

- Microstructure of the coating per ASTM F1854
- Static Tensile Strength per ASTM F1147
- Static Shear Strength per ASTM F1044
- Shear Fatigue Test per ASTM F1160
- Abrasion Resistance per ASTM F1978

The results of these tests showed that the CeSpace XP Spinal Implant System meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

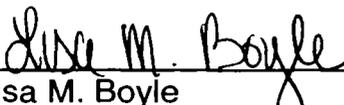
## **SUBSTANTIAL EQUIVALENCE**

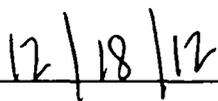
AIS believes that the Cespace XP Intervertebral Body Fusion System is substantially equivalent to the design of the Aesculap CeSpace PEEK VBR and Intervertebral Body

Fusion Systems (K083311). The Plasmapore® coating has been used and cleared in a number of legally marketed product lines manufactured by Aesculap (hip, knee, and spinal implants) for many years.

**C. PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT**  
[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as the Senior Regulatory Affairs Specialist for Aesculap® Implant Systems, 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.

  
\_\_\_\_\_  
Lisa M. Boyle  
Senior Regulatory Affairs Specialist

  
\_\_\_\_\_  
Date

\_\_\_\_\_  
Premarket Notification 510(k) Number

**D. CLASS III SUMMARY AND CERTIFICATION**

This section does not apply.

**E. FINANCIAL CERTIFICATION AND DISCLOSURE STATEMENT**

This section does not apply.

**F. DECLARATION OF CONFORMITY AND SUMMARY REPORTS**

This section does not apply.

**SECTION II**  
**GENERAL INFORMATION**

**DEVICE NAME**  
**DEVICE SPONSOR**  
**REGULATORY CLASSIFICATION**  
**PURPOSE FOR PREMARKET NOTIFICATION**  
**DEVICE DESCRIPTION**  
**INDICATIONS FOR USE**  
**SUBSTANTIAL EQUIVALENCE**  
**PERFORMANCE STANDARDS**  
**QUALITY CONTROL FUNDAMENTAL**  
**SCIENTIFIC TECHNOLOGY**  
**MANUFACTURING/STERILIZATION FACILITIES**

## II. GENERAL INFORMATION

### A. DEVICE NAME

1. Trade Name: AIS CeSpace XP Intervertebral Body Fusion System
2. Common Name: Intervertebral fusion device with Bone graft, cervical

### B. DEVICE SPONSOR

1. Est. Registration No: 3005673311
2. Name / Address: Aesculap® Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034
3. Contact Person: Lisa M. Boyle, Sr. Regulatory Affairs Specialist  
800-258-1946 x 5274  
610-791-6882 (fax)  
lisa.boyle@aesculap.com

### C. REGULATORY CLASSIFICATION

1. Device Class: Class II
2. Product Code: ODP
3. Classification Number: 888.3080
4. Classification Name: Orthosis, Spinal Intervertebral Fusion
5. Review Panel: Orthopedic

### D. PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the CeSpace XP Intervertebral Body Fusion System. The difference between the subject and predicate device is the addition of the Plasmapore® coating to the subject device.

### E. DEVICE DESCRIPTION

The Aesculap CeSpace XP Intervertebral Body Fusion System is a cervical intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of sizes to meet the requirements of the individual patient anatomy. Components are manufactured from PEEK – Optima (per ASTM F2026) with a titanium layer and a vacuum plasma spray coating (Plasmapore® - per ISO 5832-3). The device will have Tantalum markers per ASTM F-560.

### F. INDICATIONS FOR USE

The indications for use have not changed.

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed,

damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

#### **G. SUBSTANTIAL EQUIVALENCE**

AIS believes that the Cespace XP Intervertebral Body Fusion System is substantially equivalent to the design of the Aesculap CeSpace PEEK VBR and Intervertebral Body Fusion Systems (K083311). The Plasmapore® coating has been used and cleared in a number of legally marketed product lines manufactured by Aesculap (hip, knee, and spinal implants) for many years.

#### **H. PERFORMANCE STANDARDS**

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the AIS SIBD XP Spinal System is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic torsion per ASTM F2077
- Static and dynamic axial compression per ASTM F2077
- Shear resistance evaluation
- Subsidence (migration) per ASTM F2267

In addition to FDA's Spine Guidance, Aesculap has also completed non-clinical testing recommended in the "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements." The following tests were performed:

- Microstructure of the coating per ASTM F1854
- Static Tensile Strength per ASTM F1147

- Static Shear Strength per ASTM F1044
- Shear Fatigue Test per ASTM F1160
- Abrasion Resistance per ASTM F1978

The results of these tests showed that the CeSpace XP Spinal Implant System meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

#### I. **QUALITY CONTROL**

The AIS CeSpace XP Intervertebral Body Fusion System is manufactured by Aesculap AG, and distributed by AIS. These devices are manufactured and processed to applicable standards. Quality control checks are done on all finished products to ensure that product specifications are met before the product is released.

#### J. **FUNDAMENTAL SCIENTIFIC TECHNOLOGY**

There have been **no changes to the fundamental scientific technology** of the AIS CeSpace XP Intervertebral Body Fusion System . The subject device is exactly the same in design, indications, and fundamental scientific technology as the predicates.

The Aesculap titanium plasma spray (plasmapore®) coated spinal implants incorporate the same technology as other legally marketed systems (AIS SIBD XP Spinal System – K111122) with the titanium plasma spray (plasmapore®) coating. Testing done on the plasma spray (plasmapore®) coating was found to be similar in performance to previously cleared devices with the same type of coating.

#### K. **MANUFACTURING and STERILIZATION FACILITIES**

##### 1. Manufacturing Facility:

Aesculap AG  
Am Aesculap-Platz  
Tuttlingen Germany  
Tel: +497461952625  
Fax: +497461952969  
Konrad Kobel  
Vice President, Regulatory & Quality Management

##### 2. Sterilization Facility

(b) (4)



**SECTION III**  
**DEVICE DESCRIPTION**

**PRODUCT BACKGROUND**  
**SYSTEM MODIFICATIONS**  
**PRODUCT LISTING**  
**INSTRUMENTATION**

### III. DEVICE DESCRIPTION

#### A. PRODUCT BACKGROUND

The original AIS CeSpace PEEK intervertebral Body Fusion System (K083311) is an implantable spinal device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of shapes and sizes to meet the requirements of the individual patient anatomy. Components are manufactured from PEEK – Optima LT1 (per ASTM F2026). The device has Tantalum markers per ASTM F-560.

##### *When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

##### *When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

#### B. SYSTEM MODIFICATIONS

(b) (4)



(b) (4)

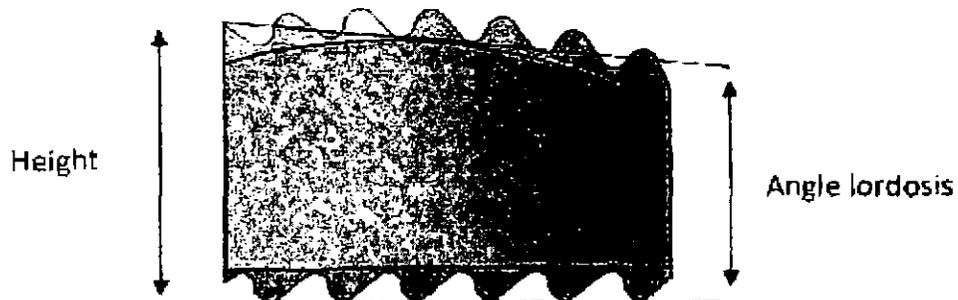
**C. PRODUCT LISTING  
CeSpace XP Implants**

The CeSpace XP implants will be offered in the following sizes:

<b>Part Number</b>	<b>Width [mm]</b>	<b>Depth [mm]</b>	<b>Height [mm]</b>	<b>Angle [°]</b>
SO245P	14	11,5	5	0°
SO246P	14	11,5	6	0°
SO247P	14	11,5	7	0°
SO248P	14	11,5	8	0°
SO249P	14	11,5	9	0°
SO250P	14	11,5	10	0°
SO251P	14	11,5	11	0°
SO252P	14	11,5	12	0°
SO254P	14	11,5	4	5°
SO255P	14	11,5	5	5°
SO256P	14	11,5	6	5°
SO257P	14	11,5	7	5°
SO258P	14	11,5	8	5°
SO259P	14	11,5	9	5°
SO260P	14	11,5	10	5°
SO261P	14	11,5	11	5°

SO262P	14	11,5	12	5°
SO265P	16	13,5	5	0°
SO266P	16	13,5	6	0°
SO267P	16	13,5	7	0°
SO268P	16	13,5	8	0°
SO269P	16	13,5	9	0°
SO270P	16	13,5	10	0°
SO271P	16	13,5	11	0°
SO272P	16	13,5	12	0°
SO274P	16	13,5	4	5°
SO275P	16	13,5	5	5°
SO276P	16	13,5	6	5°
SO277P	16	13,5	7	5°
SO278P	16	13,5	8	5°
SO279P	16	13,5	9	5°
SO280P	16	13,5	10	5°
SO281P	16	13,5	11	5°
SO282P	16	13,5	12	5°

**\*\*Drawing for the implants mentioned above can be found on the following pages.\*\***



**D. Instrumentation**

No new instruments are being introduced with the CeSpace XP implants. The system will utilize existing Aesculap instruments.









**SECTION IV**  
**SUBSTANTIAL EQUIVALENCE**

**COMPARATIVE TABLE**  
**DETERMINATION OF SUBSTANTIAL EQUIVALENCE**

**IV. SUBSTANTIAL EQUIVALENCE**

**A. COMPARATIVE TABLE**

<b>Aspect</b>	<b>Aesculap CeSpace XP Intervertebral Fusion Device (TBD)</b>	<b>Aesculap CeSpace PEEK Intervertebral Fusion Device (K083311)</b>	<b>Aesculap SIBD Spinal System (K111122)</b>
<b>Indications</b>	<p><b>Same as K083311</b></p>	<p><b>When used as a Vertebral Body Replacement Device:</b>                      The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems, such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.</p> <p><b>When used as an Intervertebral Body Fusion System:</b>                      The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the</p>	<p>The AIS SIBD XP Spinal System is a stand-alone device intended to be used with the four supplied bone screws if no supplement fixation is used.</p> <p>As an intervertebral body fusion device designed for use with autograft, the SIBD XP Spinal System is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).</p> <p>Patients should be skeletally mature and must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap® Implant Systems device.</p>

		<p>disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.</p> <p>Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap device.</p>	
<b>Material</b>	<ul style="list-style-type: none"> <li>• PEEK Optima per ASTM 2026.</li> <li>• Radiographic markers are Tantalum per ASTM F560.</li> <li>• Plasmapore Coating per ISO 5832</li> </ul>	<ul style="list-style-type: none"> <li>• PEEK Optima per ASTM 2026.</li> <li>• Radiographic markers are Tantalum per ASTM F560.</li> <li>• No coating</li> </ul>	<ul style="list-style-type: none"> <li>• PEEK Optima per ASTM 2026.</li> <li>• Radiographic markers are Tantalum per ASTM F560.</li> <li>• Plasmapore Coating per ISO 5832</li> </ul>
<b>Design</b>	Hollow column to accept bone graft. Teeth on ends to prevent migration.	Hollow column to accept bone graft. Teeth on ends to prevent migration.	Hollow column to accept bone graft. Secures to vertebral bodies by four titanium screws inserted through the anterior screw holes.
<b>Shape</b>	Oval (Cespace)	Oval (Cespace)	Anatomic
- Heights	4mm – 12mm	4mm – 12mm	10-20mm
- Widths	14mm and 16mm	14mm and 16mm	35mm & 40mm
- Depth	11.5mm and 13.5mm	11.5mm and 13.5mm	25 & 29mm
Lordosis	0° and 5°	0° and 5°	4°, 9°, and 14°

**\*\* Please note: The Aesculap SIBD predicate is only being used to show that the plasmapore® coating has been used/cleared in other Spinal devices already on the market. It should not be used for design comparison.**

**B. Determination of Substantial Equivalence: [ref. Office of Device Evaluation (ODE) Blue Book Memorandum #86-3, Attachment I "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)"]**

**New Device** [AIS CESPACe XP Spinal System ] **is Compared to the Marketed Device(s):** [AIS CESPACe Spinal System (K083311) and the AIS SIBD XP System (K111122)].

**Does New Device Have Same Indication Statements?**

**Yes.** The indications for the subject device and the AIS CESPACe Spinal System(K083311) are exactly the same.

**New Device Has Same Intended Use and May be "Substantially Equivalent".**

**Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?**

Design: **Yes.** The design/ features of the subject device and the CESPACe predicate device (K083311) are the same in system components offered, indications for use, dimensional ranges, and fundamental scientific technology.

Material: **Yes.** The materials (PEEK Optima –LT1, Titanium alloy) of the subject device are exactly the same as the materials used in the manufacturing of the predicate devices - CeSpace Spinal System (K083311) and the SIBD Spinal System (K111122)

Coating: **Yes.** The AIS CeSpace XP Spinal system contains a Plasmapore® coating. This coating is exactly the same as the coating used in the SIBD XP Spinal System (K111122) and the Aesculap Hydrolift VBR System (K083186). The plasmapore® coating has been used and cleared in a number of legally marketed systems in the US and Europe for many years.

**Could the New Characteristics Affect Safety or Effectiveness? No.**

Overall, the CESPACe XP Spinal System does not impart any new technological characteristics or features from the competitive devices. When compared to the predicate devices, the subject device demonstrates substantial equivalency in terms of coating, design, material, performance characteristics and indications for use. Performance test data can be found in Section IX.

**Substantial Equivalence Determination.**

**SECTION V**  
**LABELING INFORMATION**

**PACKAGE LABEL**  
**PACKAGE INSERT**  
**SURGICAL TECHNIQUE MANUAL**

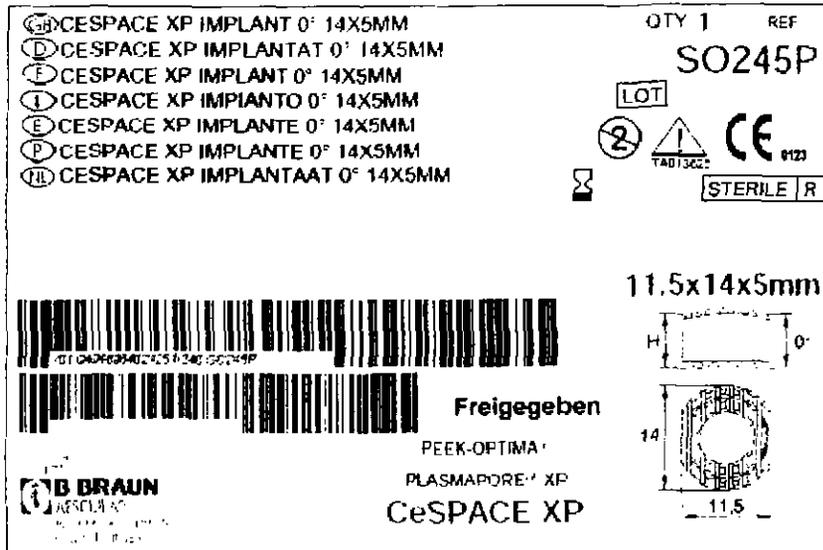
**V. LABELING INFORMATION**

**A. PACKAGE LABEL**

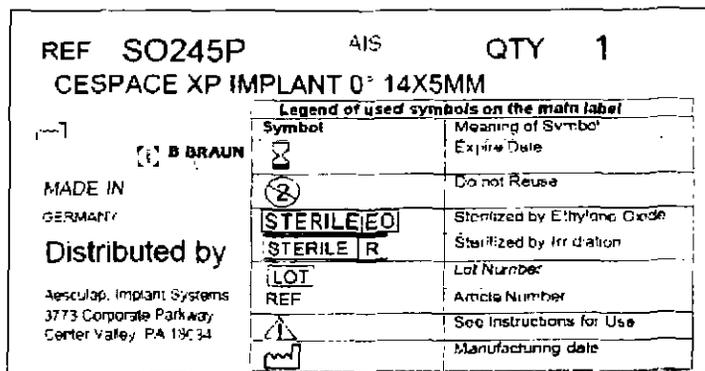
The AIS CESPACe XP Spinal System components are marked with the company name, catalog number, product description, device material, lot number, length and/or size.

The following are examples of the package labels for the implants.

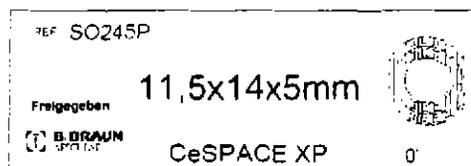
**Sample Labels for Sterile Product:**



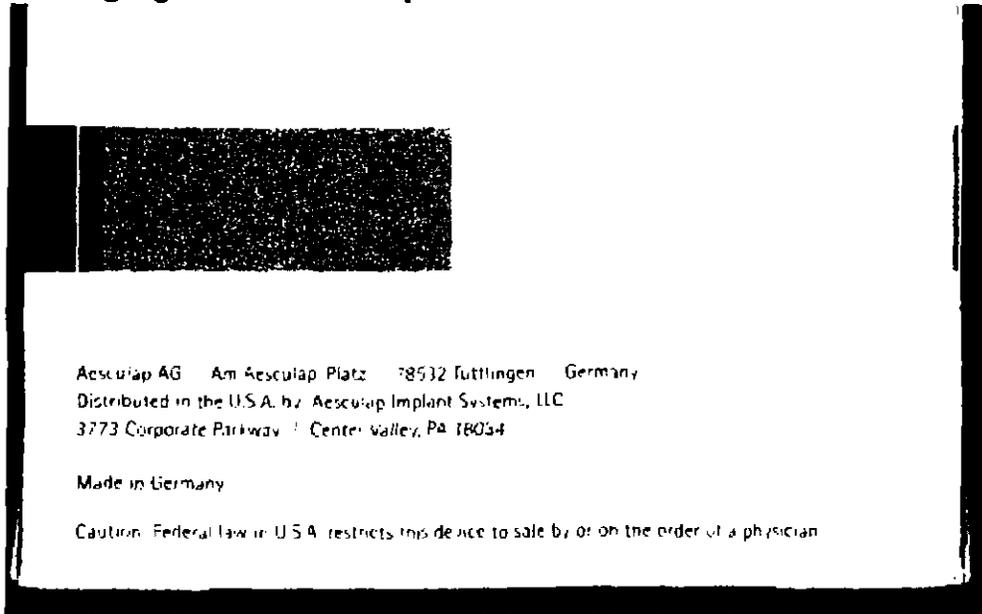
**Additional Symbol Label for Package**



**Box Label**



### Packaging box for sterile products



Aesculap AG Am Aesculap Platz 78532 Tuttingen Germany  
Distributed in the U.S.A. by Aesculap Implant Systems, LLC  
3773 Corporate Parkway Center Valley, PA 16034

Made in Germany

Caution: Federal law in U.S.A. restricts this device to sale by or on the order of a physician

**B. PACKAGE INSERT**

A copy of the package insert is located on the following pages.

**C. SURGICAL TECHNIQUE**

A copy of the draft surgical technique manual is available in Appendix A.

**Aesculap Implant Systems, LLC**

Document Number: SOP-AIS-5000648

Legacy Number: IFU

Title: AESCULAP CESPAC PEEK SPINAL IMPLANT SYSTEM

Effective Date: 4/20/2009 11:39:27 AM  
Version: CURRENT, 3.0

Page 1 of 5

## Aesculap CeSpace PEEK Spinal Implant System: Instructions for Use

### Indications for use:

#### *When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

#### *When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

### Materials

(b)(4)

### General Surgical Indications

Surgically installed implants serve to support normal healing processes. They should neither replace normal structures of the body nor permanently bear the loads occurring in the case of incomplete healing.

### Contraindications

The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the PEEK devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses

Effective

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- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

**Risks**

The surgical intervention involves the following potential risks:

- Neurological complications caused by over distraction or trauma of the nerve roots or dura
- Loss of intervertebral disk height due to removal of healthy bone material

Complications that can generally occur in connection with intervertebral surgery:

- Pseudarthrosis
- Incorrect implant position
- Spondylolisthesis
- Loss of fixation; dislocation or migration

**Side-effects and adverse interactions**

None known.

**Safety notes**

- It is the operating surgeon's responsibility to ensure that the surgical procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present documentation.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be thoroughly familiar with bone anatomy, including the pathways of nerves, blood vessels, muscles and tendons.
- Aesculap is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- The instructions for use of the individual Aesculap implant components must be observed.
- Do not use damaged or surgically excised components under any circumstances.
- Implants that have already been used must not be reused.
- Delayed healing can result in implant rupture due to material fatigue.
- The implant components are supplied with their article numbers, the name of the implant, as well as the batch number and serial number (if applicable) which should be documented in all patient records.
- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed.

**Sterility**

- The implant components come individually packed in protective packaging that is labeled according to its contents.
- The implant components have been sterilized by irradiation (min. dose 25 kGy).
- Store implant components in their original packaging. Remove them from their original protective packaging only just prior to application.
- Prior to use, check the product expiry date and verify the integrity of the sterile packaging. Do not use implant components that are past their expiry date or if the package is damaged.

**Aesculap Implant Systems, LLC**

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**Application**

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:

- Selection of the implant components and their dimensions
- Positioning of the implant components in the bone
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:

- All requisite implant components are ready to hand
- Operating conditions are highly aseptic
- The implantation instruments, including the special Aesculap implant system instruments, are complete and in working condition.
- The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready to hand.
- The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
- The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

The intervention has been explained to the patient, whose consent concerning the following information has been documented:

- In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
- The life-span of the implant depends on the patient's body weight.
- Corrective surgery may become necessary if the implant loosens.
- The patient must undergo regular check-ups of the implant components, performed by a physician.

**Implanting the PEEK devices**

- Select the appropriate PEEK implant size and shape according to the indication, the preoperative planning, and the bone situation found intraoperatively.
- Correctly apply the preparation instruments (rasps, curettes and chisels) for preparing the implant bed, as well as the implantation instrument.
- Apply appropriate care when inserting the implant.
- Check implant height and/or angle using the trial implants.

Further information on B. Braun/Aesculap implant systems is always available from B. Braun/Aesculap or the relevant B. Braun/Aesculap agency.

**WARNING**

Implants supplied in sterile condition must not be resterilized or reused under any circumstances. Danger to the patient and possible loss of implant functionality due to resterilization!

**WARNING**

Increased risk of migration due to over-preparation of the vertebral body endplates!

When preparing the implant bed, make certain that the base and cover plates of the adjacent vertebral bodies are not weakened.

**Aesculap Implant Systems, LLC**

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**CAUTION**

*Damage to the implant thread!*

- Keep to the thread axis when screwing the implant onto the insertion instrument.
- Screw in the implant as far as it will go so that the dihedron of the instrument rests in the groove on the implant.

**CAUTION**

*Based upon dynamic testing results physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the CeSpace implant when used as an intervertebral body fusion device.*

**Distributed in the U.S. by:**

Aesculap Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034

Phone: 800-234-9179

SOP-AIS-5000648 Rev. 3

Effective

**SECTION VI**  
**STERILIZATION INFORMATION**

**STERILIZATION**

## VI. STERILIZATION AND SHELF LIFE INFORMATION

### A. Sterile Device Information

The AIS CESPAC Spinal System additions presented in this submission will be packaged and sterilized under the same controls as the AIS current product line.

The AIS CESPAC Spinal System are provided sterile. The sterility of the implants can only be guaranteed providing that the packaging is properly sealed and intact. Prior to use, make certain that the package is in the aforementioned condition. Do not use the product after it has exceeded its expiration date. The implants are intended for SINGLE USE ONLY. They may not be resterilized

The SIBD XP implants are sterilized by:

(b)(4)



#### METHOD

(b) (4)



#### VALIDATION METHOD

(b) (4)



#### PYROGENICITY TESTING

(b) (4)



#### PACKAGING

The *CESPACE<sup>XP</sup> Implants* is packed in double sterile condition with a cardboard box as storage packaging. For primary and secondary packaging blisters made of PETG with TYVEK lids are used. Inside the primary packaging the products are stabilized by a folding blister with silicone inlay.

For product labeling individual product data are labeled on the Tyvek lids and cardboard box, including all necessary labeling contents.

The packaging system is validated according master validation plan **064 / 2006 / 0**, part of the packaging validation group 1.2.3 (Blister / TYVEK) and is qualified for gamma sterilization. The validation data are documented and filed in the factory department IM (BMF).

***SHELF LIFE***

Five year shelf life has been tested. and passed for this product. Therefore, sterility of five years can be concluded. Validation available upon request.

**SECTION VII**  
**BIOCOMPATIBILITY INFORMATION**

## **VII. BIOCOMPATIBILITY INFORMATION**

### **A. Materials / Biocompatibility**

(b) (4)



**SECTION VIII**  
**RISK ANALYSIS**

**A. RISK ANALYSIS**

ISO 14971 (Medical devices – Application of risk management to medical devices) was used to determine the risks. The risk analysis is located on the following pages.

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

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Records processed under FOIA Request # 2013-9924; Released by CDRH on 10-29-2015

**SECTION IX**  
**PERFORMANCE DATA**

**IX. PERFORMANCE DATA**

**A. BIOMECHANICAL TESTING**

(b) (4)

















































































































































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**APPENDIX A**

**Surgical Technique Manual**

















**APPENDIX B**

**Biocompatibility Data for the PEEK OPTIMA LT1**





























































































































































































## **APPENDIX C**

### **Predicate Device Information**

K083311

Page 1 of 2

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

***Aesculap CeSpace PEEK Spinal Implant System***

*7 November 2008*

**MAR - 4 2009**

**COMPANY:** Aesculap® Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Matthew M. Hull  
800-258-1946 (phone)  
610-791-6882 (fax)

**TRADE NAME:** Aesculap CeSpace PEEK Spinal Implant System

**COMMON NAME:** Intervertebral Fusion Device w/ Bone Graft, Cervical

**CLASSIFICATION NAME:** Orthosis, Spinal Intervertebral Fusion

**REGULATION NUMBER:** 888.3080

**PRODUCT CODE:** ODP, MQP

**SUBSTANTIAL EQUIVALENCE**

Aesculap® Implant Systems, Inc. believes that the Aesculap Cespace PEEK Spinal Implant System is substantially equivalent to the Aesculap PEEK VBR and Intervertebral Body Fusion Systems (K060762 & K071983), the Spinal Elements Crystal cervical interbody fusion devices (K073351).

**DEVICE DESCRIPTION**

The Aesculap CeSpace PEEK Spinal Implant System is a cervical intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of sizes to meet the requirements of the individual patient anatomy. Components are manufactured from PEEK – Optima (per ASTM F2026).

**INDICATIONS FOR USE**

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

K083311

Page 2 of 2

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The implants in the Aesculap CeSpace PEEK Spinal Implant System are offered in the same range of shapes and sizes as the predicate devices. The material used for the Aesculap device is the same as that used to manufacture the predicate devices.

**PERFORMANCE DATA**

Static and dynamic testing of the Aesculap PEEK Spinal Implant System was performed in accordance with ASTM F2077 and/or F1717 as recommended by the FDA Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Aesculap® Implant System, Inc.  
% Mr. Matthew M. Hull  
3733 Corporate Parkway  
Center Valley, Pennsylvania 18034

MAR 4 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Re: K083311

Trade/Device Name: Aesculap CeSpace PEEK Intervetebral Body Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: II  
Product Code: ODP  
Dated: February 10, 2009  
Received: February 11, 2009

Dear Mr. Hull:

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

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

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

Page 2 – Mr. Matthew M. Hull

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

Enclosure

**A. INDICATIONS FOR USE STATEMENT**

510(k) Number: K083311

**Device Name: Aesculap CeSpace PEEK Intervertebral Body Fusion System**

**Indications for Use:**

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

Prescription Use     X     and/or Over-the-Counter Use                       
(per 21 CFR 801.109)

**(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, Res:**  
**and Neurological Device:**

510(k) Number K083311



K11122

**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

AUG - 4 2011

***Aesculap® Implant Systems(AIS) – SIBD XP Spinal System  
August 1, 2011***

**COMPANY:** Aesculap® Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 3005673311

**CONTACT:** Lisa M. Boyle  
610-984-9274 (phone)  
610-791-6882 (fax)

**TRADE NAME:** AIS SIBD XP Spinal System

**COMMON NAME:** Intervertebral Body Fusion Device

**CLASSIFICATION NAME:** Intervertebral Fusion Device with Integrated Fixation,  
Lumbar

**REGULATION NUMBER:** 888.3080

**PRODUCT CODE:** OVD

**PURPOSE FOR PREMARKET NOTIFICATION**

The purpose for this submission is to gain marketing clearance for the AIS SIBD XP Spinal System.

**SUBSTANTIAL EQUIVALENCE**

Aesculap® Implant Systems, Inc. believes that the AIS SIBD XP Spinal System is substantially equivalent to the design of the AIS SIBD Spinal System (K100802). The Plasmapore® coating used for the subject device is similar to the the Plasmapore® coating of the AIS Hydrolift VBR System (K083186). Furthermore, the coating has been used and cleared in a number of legally marketed systems in the US and Europe for many years.

**DEVICE DESCRIPTION**

The AIS SIBD XP Spinal System is an implantable spinal device manufactured from PEEK-OPTIMA® LT (Polyetheretherketone) per ASTM F2026, with a titanium layer and a vacuum plasma spray coating (Plasmapore®). The device will have Tantalum markers per ASTM F-560. The implant is secured to vertebral bodies by four titanium screws inserted through the anterior screw holes. The implants are offered in a variety of shapes and sizes to meet the requirements of the individual patient anatomy.

page 1 of 3

K11122

### **INDICATIONS FOR USE**

The AIS SIBD XP Spinal System is a stand-alone device intended to be used with the four supplied bone screws if no supplemental fixation is used.

As an intervertebral body fusion device designed for use with autograft, the SIBD XP Spinal System is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).

Patients should be skeletally mature and must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap® Implant Systems device.

### **TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

The components of the SIBD XP Spinal System are offered in the same range of shapes and sizes as the predicate device. The material used for the Aesculap® Implant Systems device is the same as that used to manufacture the predicate devices. The only difference between the predicate device and the subject device is the titanium layer and a vacuum plasma spray coating (Plasmapore®).

### **PERFORMANCE DATA**

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the AIS SIBD XP Spinal System is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic torsion per ASTM F2077
- Static and dynamic axial compression per ASTM F2077
- Static and dynamic shear compression testing per ASTM F2077
- Subsidence per ASTM F2267
- Wear Debris per ASTM F2077 & ASTM F1877
- Expulsion per ASTM Draft Standard F-04.25.02.02

In addition to FDA's Spine Guidance, Aesculap has also completed non-clinical testing recommended in the "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements." The following tests were performed:

- Microstructure of the coating per ASTM F1854
- Static Tensile Strength per ASTM F1147
- Static Shear Strength per ASTM F1044

page 2 of 3

K11122

- Shear Fatigue Test per ASTM F1160
- Abrasion Resistance per ASTM F1978

The results of these tests showed that the AIS SIBD XP Spinal System meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

Page 3 of 3



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

Aesculap Implant Systems, Inc.  
% Ms. Lisa M. Boyle  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

AUG - 4 2011

Re: K111122

Trade/Device Name: Aesculap® Implant Systems (AIS) – SIBD XP Spinal System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: OVD  
Dated: July 08, 2011  
Received: July 11, 2011

Dear Ms. Boyle:

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

Page 2 – Ms. Lisa M. Boyle

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

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) 796-7160 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

510(k) Premarket Notification

SIBD XP Spinal System  
(Plasmapore® Coated)

Page 1 of 1

**A. INDICATIONS FOR USE STATEMENT**

510(k) Number: K111122

**Device Name: Aesculap® Implant Systems (AIS) – SIBD XP Spinal System**

**Indications for Use:**

The AIS SIBD XP Spinal System is a stand-alone device intended to be used with the four supplied bone screws if no supplemental fixation is used.

As an intervertebral body fusion device designed for use with autograft, the SIBD XP Spinal System is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).

Patients should be skeletally mature and must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap® Implant Systems device.

Prescription Use   X   and/or Over-the-Counter Use             
(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Signature for MAM 8/3/11*

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

510(k) Number K111122



## COVER SHEET MEMORANDUM

**From:** Reviewer Name Katherine Kavlock  
**Subject:** 510(k) Number K123909  
**To:** The Record

**Please list CTS decision code:** SE - Substantially Equivalent

- Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page ( <i>Attach IFU</i> )	X	
510(k) Summary or 510(k) Statement ( <i>Attach Summary or Statement</i> )	X	
Truthful and Accurate Statement ( <i>Must be present for a Final Decision</i> )	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach <u>Form 3654</u> .)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See <u>Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices</u> .)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		×
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		×

**Regulation Number:** 21 CFR 888.3080  
**Class:** II  
**Product Code:** ODP  
**Additional Product Codes:**

**Digital Signature Concurrence Table**  
 (Not all signatures may be required)

Branch Chief Sign-Off	Anton E. Dmitriev 2013.04.15 15:54:25 -04'00' 
Division Sign-Off	Erin I. Keith 2013.04.15 16:01:44 -04'00' 



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MEMORANDUM**

Food and Drug Administration  
Office of Device Evaluation  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

**Premarket Notification 510(k) Review  
Traditional**

**K123909/S001**

Date: April 12, 2013

To: The Record

From: Katherine Kavlock, Biomedical Engineer

Office: ODE

Division: DOD/ASDB

510(k) Holder: Aesculap Implant Systems, Inc  
Device Name: Aesculap CeSpace XP  
Contact: Lisa Boyle, Senior Regulatory Affairs Specialist  
Address: 3773 Corporate Parkway  
Center Valley, PA 18034  
Phone: 610.984.9274  
Fax: 610.791.6882  
Email: [lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com)

**Recommendation: Substantially Equivalent (SE)**

**I. Purpose and Submission Summary**

This 510(k) seeks to introduce into interstate commerce the Aesculap CeSpace XP into interstate commerce. The Aesculap CeSpace XP is a new version of the sponsor's previously cleared CeSpace PEEK spacer with an additional Ti coating (Plasmapore). The sponsor was previously asked to state the purpose of the coating (K111122) and they stated that they did not want to make any claims regarding bone in/on growth or osseointegration<sup>(b)(4)</sup>

Additionally, the sponsor has not provided all the required performance testing. The sponsor will be asked to analyze their dynamic test solution for the presence of particulate and explain why the test results of the subject coated spacer are inferior to the predicate PEEK spacer or provide additional side-by-side testing. For the reasons listed above, I recommend that the Aesculap CeSpace XP spacer be put on **Telephone Hold (TH)** until the sponsor has provided the requested additional information.

**S001 Update:**

<sup>(b)(4)</sup>

Additionally, the sponsor has responded adequately to our deficiencies concerning characterization of possible wear debris/particulate and seemingly inferior mechanical properties, particularly in torsion, of the subject device compared to the sponsor's own un-coated predicate. In light of the new information provided in S001, I recommend that the CeSpace XP implant be found **Substantially Equivalent (SE)** to a legally marketed cervical intervertebral body fusion device and I recommend that the sponsor be sent an advisory regarding .

**II. Administrative Requirements**

		Yes	No	N/A
Indications for Use page (Indicate if: <b>Prescription</b> or OTC)	(Page 002)	X		
Truthful and Accuracy Statement	(Page 006)	X		
510(k) Summary or 510(k) Statement	(Page 003)	X		
Standards Form		X		

**III. Device Description**

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

The purpose of this 510(k) is to communicate the intent of Aesculap Implant Systems to market a new version of their PEEK cervical intervertebral body fusion device with a Ti coating.



**Figure 1:** CeSpace XP (subject device; left) and CeSpacer PEEK spacer (predicate device; right).

The subject CeSpace XP spacers are circular-shaped with a large central hole for placement of autogenous bone graft to encourage bony fusion through the construct. The superior and inferior surfaces have wedge teeth to minimize the risk of migration. These devices are manufactured from PEEK Optima-LT1 with tantalum radiographic markers and Ti coating. In a process similar to the sponsor's lumbar intervertebral body fusion device with integrated fixation, the original CeSpace PEEK spacer is roughened via grit blasting and then a thin layer of titanium is applied via Physical Vapor Deposition (PVD). This coating method produces a thin (4 µm) titanium (Ti Grade 2 per Iso

5832-2) coating mechanically bonded to the surface of the PEEK implant. After the PVD coating, an additional coating of plasma sprayed titanium alloy powder (Ti-6Al-4V conforming to ISO 5832-3) is deposited via Vacuum Plasma Spray (VPS). The VPS coating, known as Plasmapore, is approximately 95 µm thick with an average porosity of 46%. The coating is applied to all surfaces with the exception of the inserter attachment area and the inside of the central graft hole.

A table of system components with part numbers can be found in Section III (page 014) of the original submission. The sponsor proposes to offer the subject device in the following range of sizes:

*Footprint:* 14 mm x 11.5 mm or 16 mm x 13.5 mm

*Heights:* 4 - 12 mm (1 mm increments)

*Angulation:* 0° or 5°\*

\*0° implants offered in 5-12 mm heights.

#### Instruments

The sponsor states that no new instruments are being introduced with the CeSpace XP implants. The system will utilize the existing CeSpace instruments cleared in K083311.

#### Engineering Drawings

Engineering drawings of the CeSpace XP implants are included in Section III (pages 016-019).

#### Materials

(b) (4)



(b) (4)

**IV. Indications for Use**

*When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

*When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

(b) (4)

**V. Predicate Device Comparison**

The sponsor identified their own PEEK cervical spacer (CeSpace PEEK, K083311) and lumbar coated stand-alone cage (K111122) as the predicates for the subject device. The sponsor discussed substantial equivalence and provided a comparison table in Section 16 (pages 57-58) of the original submission (summarized below).

Property	CeSpace XP (subject device)	CeSpace PEEK (K083311)	SIBD XP Spinal System (K111122)
<b>Indication for Use</b>	The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.	The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.	

	***Also has VBR indications	***Also has VBR indications	
<b>Material</b>	PEEK Optima-LT1 cage with Plasmapore (Ti) coating	PEEK Optima-LT1	PEEK Optima-LT1 cage with Plasmapore (Ti) coating
<b>Footprint</b>	14 mm x 11.5mm 16 mm x 13.5 mm	14 mm x 11.5mm 16 mm x 13.5 mm	25 x 35 mm 29 x 40 mm
<b>Lordosis</b>	0 or 5°	0 or 5°	4, 9, and 14°
<b>Height</b>	4 - 12 mm	4 - 12 mm	10 - 20mm (2mm increments)
<b>Sterility</b>	Provided Sterile	Provided Sterile	Provided Sterile

**VI. Labeling**

Draft labeling (package insert and surgical technique manual) is provided in an email (attached) from the sponsor in response to the RTA Checklist. Sample outer box labels are provided in Section V (page 025).

LABEL

- Component & system name
- Material
- Part number/Lot number
- Single use statement
- Sterile notation
  
- Shelf life
- Statement referring to package insert for labeling limitations
- Cautionary symbol/notation restricting sale to a physician
- Company name and address

INSERT

- System name
- Material
- Indications for use, including levels of fixation
- Single use statement
- Sterilization parameters and cleaning instructions
- Contraindications, warnings and precautions
- Appropriate warnings for product code
- Company name, address & telephone number
- Cautionary statement restricting sale to a physician
- Statement indicating how to obtain surgical technique manual
- MR compatibility/warning

SURGICAL TECHNIQUE MANUAL

- Device description
- Contraindications, precautions and warnings
- Magnified sketches of important steps
- Indications and intended use
- Removal/revision procedures

(b) (4)



**VII. Sterilization/Shelf Life/Reuse**

(b)(4)



(b)(4)



(b) (4)



**VIII. Biocompatibility**

The subject device components are manufactured from PEEK Optima-LT1 per ASTM F2026, Tantalum per ASTM F560, Ti Grade 2 per ISO 5832-2 and Titanium alloy (Ti-6Al-4V) per ISO 5832-3.

(b) (4)



**IX. Software**

Not Applicable

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

The sponsor has not stated that the CeSpace XP implants have not been evaluated for safety, compatibility, heating or migration in the MR environment.

(b) (4)

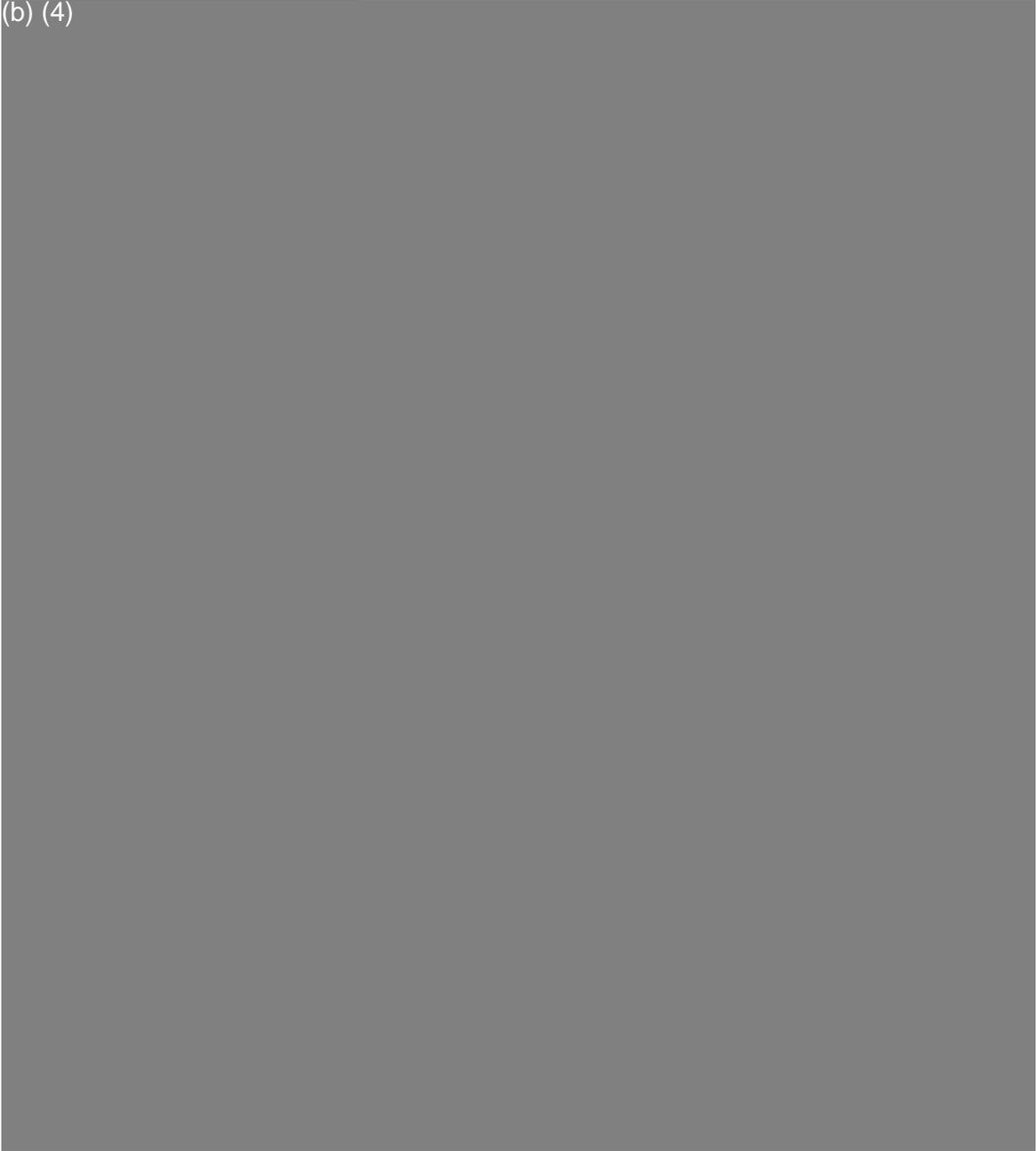


(b) (4)

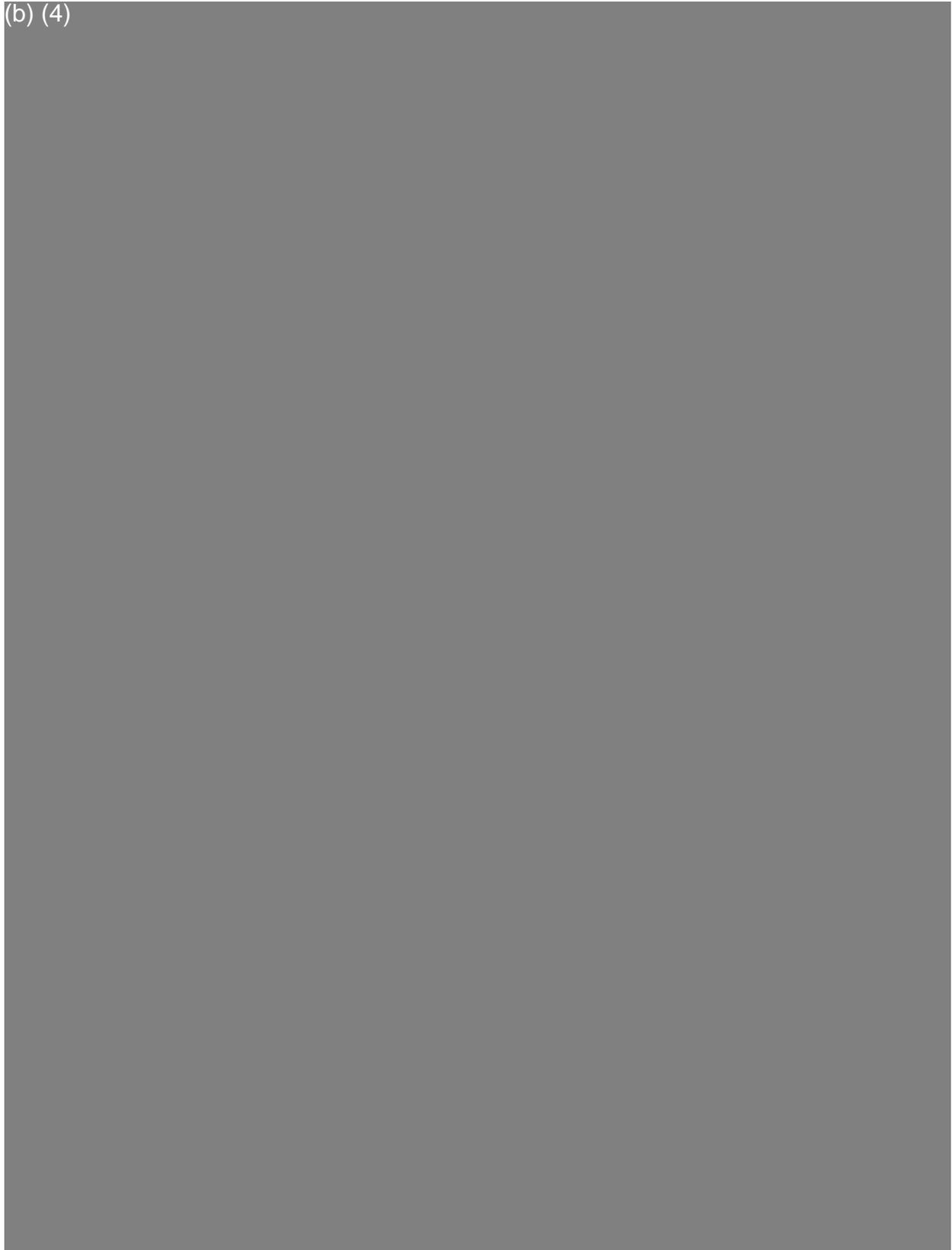
A large rectangular area of the document is redacted with a solid grey fill.

**XI. Performance Testing – Bench**

(b) (4)

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(b) (4)



(b) (4)

**XII. Performance Testing – Animal**

No animal data required at this time.

**XIII. Performance Testing – Clinical**

No clinical data required at this time.

**XIV. Substantial Equivalence Discussion**

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?		X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	X		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?			If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	X		If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

1. Explain how the new indication differs from the predicate device's indication: *N/A*
2. Explain why there is or is not a new effect or safety or effectiveness issue: *N/A*
3. Describe the new technological characteristics:  
*The subject device contains a Ti coating called Plasmapore.*

4. Explain how new characteristics could or could not affect safety or effectiveness:  
*The subject device utilizes a titanium coating that may create new risks of wear or flaking not present in the predicate device.*
5. Explain how descriptive characteristics are not precise enough: *N/A*
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:  
*The subject device utilizes a plasma-sprayed titanium coating, which is commonly seen in orthopedic implants; however, with this coating, there is a risk that additional wear particulates may be formed in the event that fusion does not occur. This risk is present in other intervertebral cages that may have titanium-polymer interfaces; therefore, the questions of safety and effectiveness are not new to this device type.*
7. Explain why existing scientific methods can not be used: *N/A*
8. Explain what performance data is needed:.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *N/A*  
*The sponsor has provided a characterization of the coating properties, a wear debris analysis, and mechanical testing per ASTM F2077. These analyses indicate the subject device performs equivalently or better than a legally marketed predicate device.*

(b) (4)



(b) (4)



**XVI. Contact History**

1/4/2013 - Email to sponsor requesting missing elements identified during RTA review.  
1/10/2013 - Email from sponsor with response to RTA Checklist  
2/15/2013 - Email to sponsor with Telephone Hold deficiencies

**XVII. Attachments**

Marketing brochure showing osteoconductive claims  
Sponsor response to RTA Checklist  
RTA Checklist

**XVIII. Recommendation**

**Substantially Equivalent (SE)**

Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Codes: ODP

<b>Digital Signature Concurrence Table</b>	
Reviewer Sign-Off	Katherine D. Kavlock 2013.04.15 10:17:29 -04'00'
Branch Chief Sign-Off	
Division Sign-Off	

K123909/S1



FDA CDRH DMC

MAR 14 2013

Received

March 13, 2013

Ms. Katherine Kavlock  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluation  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Springs, MD 20993-0002

Re: K123909 – CeSpace PEEK IBFD System (Plasmapore® Coated)

Dear Ms. Kavlock,

The following information is provided in response to your request for addition information received on February 15, 2013. The request for information is presented in bold lettering, with Aesculap's response following directly below.

(b) (4)



Aesculap Implant Systems, LLC  
3773 Corporate Parkway  
Center Valley, PA 18034  
Phone: 800-234-9179  
www.aesculapimplantsystems.com

Aesculap Implant Systems, LLC - a B. Braun company

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

001

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(b) (4)



(b) (4)



The Ecopy is an exact duplicate of the paper copy. If you have any questions or require additional information, please do not hesitate to contact me directly via phone at (610) 984-9274 or e-mail at [lisa.boyle@aesculap.com](mailto:lisa.boyle@aesculap.com)

Sincerely,



Lisa M. Boyle  
Sr. Regulatory Affairs Specialist

Enclosure

003



March 13, 2013

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A large, solid grey rectangular redaction box covers the majority of the page content, starting below the introductory paragraph and extending nearly to the bottom of the page.

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Enclosure

## **ATTACHMENT A**

### **Reference**

1. Albrektsson, T., and Johansson C. "Osteoinduction, osteoconduction and osseointegration." Euro Spine Journal (2001) 10:S96-S101

T. Albrektsson  
C. Johansson

# Osteoinduction, osteoconduction and osseointegration

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**Abstract** Osteoinduction is the process by which osteogenesis is induced. It is a phenomenon regularly seen in any type of bone healing process. Osteoinduction implies the recruitment of immature cells and the stimulation of these cells to develop into preosteoblasts. In a bone healing situation such as a fracture, the majority of bone healing is dependent on osteoinduction. Osteoconduction means that bone grows on a surface. This phenomenon is regularly seen in the case of bone implants. Implant materials of low biocompatibility such as copper, silver and bone cement shows little or no

osteoconduction. Osseointegration is the stable anchorage of an implant achieved by direct bone-to-implant contact. In craniofacial implantology, this mode of anchorage is the only one for which high success rates have been reported. Osseointegration is possible in other parts of the body, but its importance for the anchorage of major arthroplasties is under debate. Ingrowth of bone in a porous-coated prosthesis may or may not represent osseointegration.

**Keywords** Osteoinduction · Osteoconduction · Osseointegration

## Introduction

The terms osteoinduction, osteoconduction and osseointegration are frequently, but not always correctly, used terms in many orthopaedic papers. To give but one example of incorrect terminology, arthroplasties are commonly claimed to be osseointegrated based only on radiographic evidence, despite the fact that the resolution of radiography alone is too poor to determine whether an implant is osseointegrated or not. The aim of this paper is to first briefly explain and define these terms and then to look at them in some detail. Osteoinduction, osteoconduction and osseointegration are now the subject of much discussion, e.g. in connection with bone morphogenic proteins (BMP), bone growth factors and direct bone anchorage, respectively. Suggested definitions of the terms osteoinduction, osteoconduction and osseointegration read as follows:

*Osteoinduction.* This term means that primitive, undifferentiated and pluripotent cells are somehow stimulated to develop into the bone-forming cell lineage. One proposed definition is the process by which osteogenesis is induced [43].

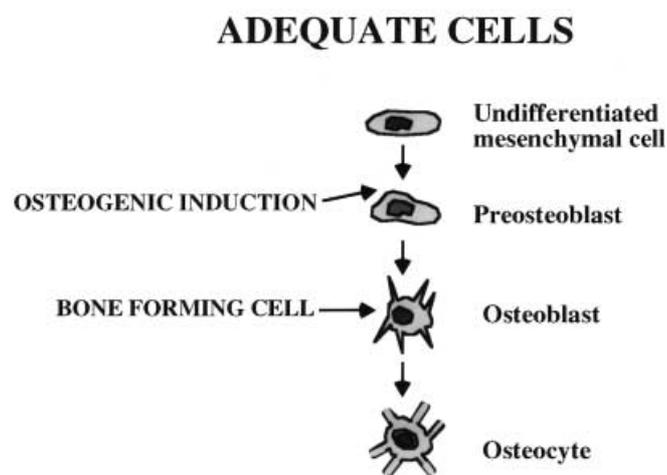
*Osteoconduction.* This term means that bone grows on a surface. An osteoconductive surface is one that permits bone growth on its surface or down into pores, channels or pipes. Wilson-Hench [43] has suggested that osteoconduction is the process by which bone is directed so as to conform to a material's surface. However, Glantz [18] has pointed out that this way of looking at bone conduction is somewhat restricted, since the original definition bears little or no relation to biomaterials.

*Osseointegration.* This was first described by Brånemark and co-workers [12]. The term was first defined in a paper by Albrektsson et al. [4] as direct contact (at the light mi-

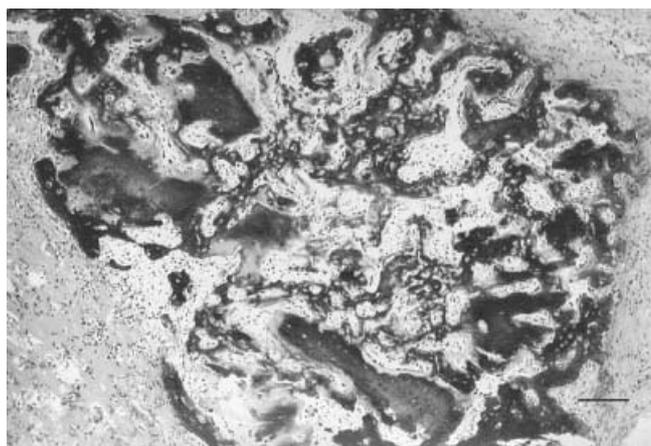
roscope level) between living bone and implant. Osseointegration is also histologically defined in *Dorland's Illustrated Medical Dictionary* as the direct anchorage of an implant by the formation of bony tissue around the implant without the growth of fibrous tissue at the bone-implant interface. Since the histological definitions have some shortcomings, mainly that they have a limited clinical application, another more biomechanically oriented definition of osseointegration has been suggested: "A process whereby clinically asymptomatic rigid fixation of alloplastic materials is achieved, and maintained, in bone during functional loading" [46]. The rigid fixation of an implant in orthopaedic praxis can be determined using radio-stereophotogrammetric (RSA) techniques and, at least in craniofacial implantology, resonance frequency analysis (RFA) [28].

### Osteoinduction and its importance for bone healing

In addition to the differentiated bone cells, i.e. osteoblasts, osteoclasts and osteocytes, bone and adjacent tissues contain a number of less differentiated cells. These undifferentiated cells are of utmost importance for proper bone healing or anchorage of an implant, since they can be recruited to form osteoprogenitor cells [45] and, with time, develop into differentiated bone cells (Fig. 1). With the correct stimulus (the inductive agent), an undifferentiated mesenchymal cell can be transformed into a preosteoblast, a process which constitutes bone induction. The classical papers describing bone induction at various host sites were published a long time ago [20, 25, 40]. These authors used gall bladder epithelium, alcohol extracts of bone and transplants to muscles or the anterior chamber of the eye, re-



**Fig. 1** At the time of injury, adequate cells for bone repair are both undifferentiated and differentiated bone cells. The majority of newly formed bone depends on the undifferentiated cells that are induced to become preosteoblasts



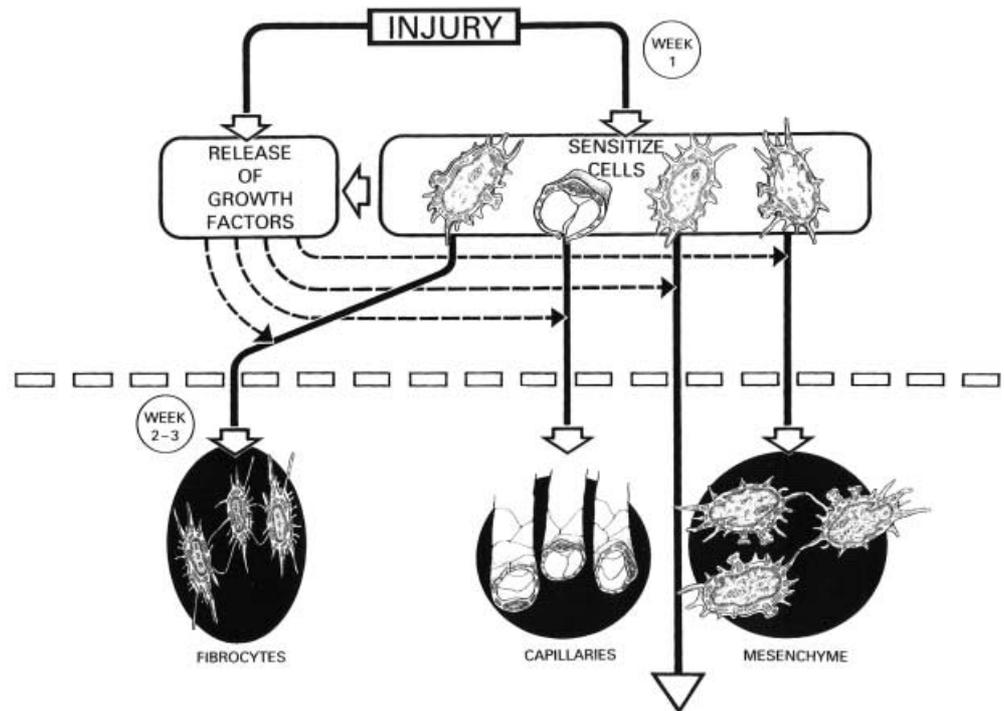
**Fig. 2** The best way to demonstrate whether a specific agent is osteoinductive is to inject it into a soft tissue pouch, where bone formation does not occur under normal conditions. BMP-7 induced bone formation 19 days after injection into a subcutaneous site in a rat. Toluidine blue. Bar, 100  $\mu$ m

spectively, to demonstrate heterotopic bone formation. The safest way to demonstrate whether a particular agent is osteoinductive or not is still to inject it into a heterotopic bed such as a muscle pouch and to analyse any potential bone formation (Fig. 2). Inductive agents naturally function in bone surroundings too, but it is difficult to differentiate between bone induction and bone conduction in an orthotopic site.

More modern research into osteoinduction dates back to Urist's experiment in the mid-1960s [39]. Demineralised bone was used as an osteoinductive agent. Later, Urist et al. [41] isolated a soluble glycoprotein called BMP as the inductive agent. The BMP belong to the transforming growth factor (TGF)- $\beta$ -family of growth factors. There are at least 15 different BMP [34], of which BMP-2 and BMP-7 seem to be particularly interesting. To date, a great number of research projects involving various types of BMP are being conducted (for reviews, see [24, 34]). BMP are naturally released in response to trauma or at bone remodelling and are the only known inductive agents [26]. However, physical stimuli such as stress or types of electrical signals otherwise applied have been regarded as, directly or indirectly, influencing bone induction [10, 13, 14, 44].

Osteoinduction, i.e. the recruitment of immature cells and the stimulation of these cells to develop into preosteoblasts, is a basic biological mechanism that occurs regularly, e.g. in fracture healing and implant incorporation. Even if pre-existing osteoblasts (i.e. before the injury) may help to form new bone, it is generally agreed that such pre-existing cells only contribute a minor portion of the new bone needed in a fracture-healing situation [16, 17]. According to Frost [16, 17] (Fig. 3), the inevitable bone, marrow and soft tissue injury triggers the subsequent repair by sensitising different types of surviving cells. Si-

**Fig.3** According to Frost's theory, injury triggers off a healing response by the release of growth factors and sensitising of cells. This is a primitive healing response with stimulation of many different types of cells



multaneously, the injury releases local, biochemical and biophysical messengers that help cells to respond and that guide them to respond in the proper manner. Some of these messengers guide the differentiation and organisation of cells, while others provide mitogens. This initial part of the healing response thus includes osteoinduction, a process that starts immediately after the injury and is very active during the first week thereafter, even though the action of the newly recruited preosteoblasts is not obvious until several weeks later, in the callus stage.

### Osteoconduction and its importance for bone healing

Bone growth on an implant surface depends on the action of differentiated bone cells. These cells may originate either in pre-existing preosteoblasts/osteoblasts that are activated by trauma or in cells recruited from primitive mesenchymal cells by osteoinduction [16, 17]. In the practical situation, therefore, osteoconduction (Fig. 4) depends to a fairly large extent on previous osteoinduction. The debate concerning whether or not a particular biomaterial acts as an osteoinductor may be slightly academic, since the injury at placement is sufficient to recruit previously undifferentiated bone cells.

Various types of bone growth factors are necessary for bone formation. Furthermore, bone growth, including bone conduction, does not occur without a proper blood supply. Albrektsson [1] studied bone conduction and remodelling in vivo and came to the conclusion that so-called full vascularisation was necessary for bone formation. It is there-



**Fig.4** In biomaterials science, osteoconduction means growth of bone on the surface of a foreign material, as seen in the lower part of this titanium screw implant (arrows). Distance between thread peaks, 600 µm

fore not surprising that the principal action of many growth factors is both mitogenic and angiogenic [37]. Growth factors that regulate bone tissue in one way or another include insulin-like growth factor (IGF I, II), fibroblast growth factor (FGF), TGF- $\beta$  and platelet-derived growth factor (PDGF). The IGF are also called somatomedins. The growth factors are small proteins that serve as signalling agents for cells [37] (see the paper by Lind, this volume, for a more detailed discussion of various growth factors).

However, in the case of implants, bone conduction is not only dependent on conditions for bone repair, but also on the biomaterial used and its reactions. Bone conduction is not possible on certain materials such as copper and silver [3]. However, bone conduction is seen with biomaterials not regarded as ideal from the point of view of biocompatibility, such as stainless steel [22] and obviously materials of high biocompatibility such as commercially pure (c.p.) titanium. Bone conduction on implants may be quantified. There is a significant difference in the amount of bone that grows on seemingly similar materials such as c.p. titanium and titanium 6-aluminum 4-vanadium [23]. However, the clinical implications of this difference remain unknown.

### Osseointegration of implants

Brånemark, who introduced this term, suggested the spelling “osseointegration” instead of “osteointegration”, and the original spelling is preferred in this paper. Osseointegration is not an isolated phenomenon, but instead depends on previous osteoinduction and osteoconduction. Thus materials that are too toxic to allow osteoconduction will not be osseointegrated either. However, many materials show at least some bone attachment, which has inspired bone pathologists to regard osseointegration as a simple foreign body reaction [15], whereas more clinically oriented scientists have rejected such a view. Osseointegrated implants have undergone a real breakthrough in oral and craniofacial implantology, yielding excellent functional results, in contrast to alternatively anchored implants, which have generally shown very poor success rates [6, 12, 35, 36]. Even if initial osseointegration is dependent on bone induction and conduction, the term implies that the bone anchorage is maintained over time. Cylindrical implant designs (without threads), rough plasma-sprayed surfaces and overloading represent factors that may lead to secondary failure of osseointegration [2, 4].

The ultrastructure of the bone–titanium interface in osseointegration demonstrates an amorphous layer from 20–40 to 500 nm thick. Some investigators [5] have described collagen and calcified tissue in this zone, whereas others [32] have failed to verify these findings. This zone is too narrow to be seen at the light microscope level of resolution. At the light microscope level, direct bone contact, osteogenesis and bone resorption occur simultaneously

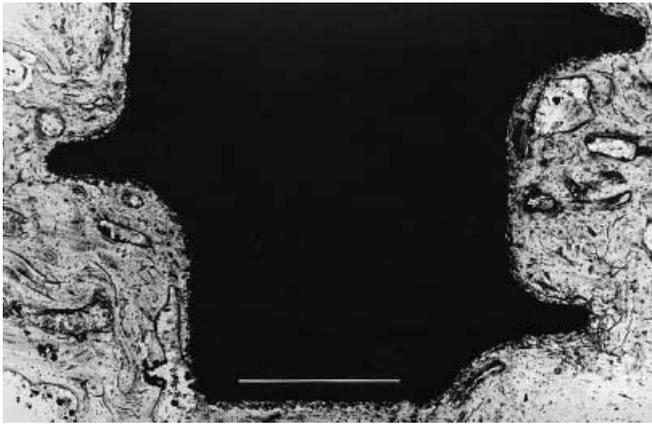


**Fig. 5** Simultaneous bone formation and resorption at the interface between bone (B) and a commercially pure titanium (c.p. Ti) implant. There are three cavities arranged in a horizontal line in the middle of the figure. In the left cavity, red dominates, i.e. positive staining for acid phosphatase meaning active bone resorption. In the middle cavity, blue dominates, i.e. positive staining for alkaline phosphatase, meaning active bone formation. In the right cavity, there is red and blue staining, i.e. both bone formation and resorption. Bar, 100  $\mu$ m

[31] (Fig. 5). From a purely biomechanical viewpoint, Skalak and Zhao [33] have demonstrated that when a hole slightly smaller than the implant diameter is prepared for implant placement, force-fitting stress increases installation torque and initial stability can be induced at a similar magnitude as seen with roughened implants.

Oral implants retrieved from patients despite remaining stability have shown that there does not seem to be 100% bone attachment. Implants retrieved after clinical function for up to 17 years showed an average of 70–80% bone contact with an absolute minimum of 60% [7]. Functioning osseointegrated implants demonstrate interfacial bone density similar to that of the bone in which the implant was implanted [38]. Even if long-term functioning osseointegrated implants show what seems to be similar bone tissue reactions, osseointegration might be able to be achieved more rapidly than otherwise observed. Such potentially accelerated osseointegration has been indicated by results from experiments with hydroxyapatite coating [19], using intermediary roughened implants [42], after hyperbaric oxygen treatment [30] or by using anodised c.p. titanium with artificially enhanced oxide layers [9]. Acceleration of osseointegration may depend on the removal of negative tissue conditions or optimisation of the biomaterial rather than on an actual increase in the rate of bone response.

Much less attention has been paid to the possibility of establishing osseointegration in orthopaedic surgery than in oral and craniofacial surgery. The original notion that polymerised bone cement may be histologically osseointegrated has not been confirmed in more recent investigations [29]. Histological sections to reveal true bone-to-im-



**Fig. 6** Hydroxyapatite-coated vertebral screw in a goat. Osseointegration is evident. *Bar*, 1000  $\mu\text{m}$  (Courtesy of Dr. B. Sandén, Uppsala University)

plant contact need to be quite thin (of the order of 10–20  $\mu\text{m}$ ) to really reveal osseointegration. Thicker sections have a shadow effect [21] that make it impossible to state whether or not true direct bone contact has been achieved. Apart from poor resolution, this is the reason why common radiographs are of little value in the diagnosis of osseointegration. The question is whether it is really possible to establish osseointegration of conventional orthopaedic arthroplasties with the combined use of less biocompatible materials, interfacial heat due to curing bone cement, drilling or reaming without a cooling agent and too rapid

loading. It is known that interfacial implant movement of more than 150  $\mu\text{m}$  will inevitably lead to soft tissue formation instead of bone, for instance [11]. Even if one- or two-point bone contact can be demonstrated, this need not represent actual osseointegration of the entire implant.

Screw-type implants inserted using a modified minimally traumatising technique have been convincingly osseointegrated, e.g. in hip arthroplasties [8] and interphalangeal implants [27] or vertebral screws (Fig. 6). However, whether or not osseointegration will become as important a type of anchorage in orthopaedics as in oral and craniofacial implantology will depend on the reported long-term clinical results of this type of anchorage.

## Conclusion

Osteoinduction, osteoconduction and osseointegration are interrelated, but not identical phenomena. Osteoinduction is part of normal bone healing and is responsible for the majority of newly formed bone, e.g. after a fracture or the insertion of an implant. The implant itself may be osteoinductive, but this is not a prerequisite for bone induction. Osteoconduction is a term now usually used in conjunction with implants. Osteoconduction and osseointegration both depend not only on biological factors, but also on the response to a foreign material. The osteoconductive response may be rather short lived, but successful osseointegration maintains its bone anchorage over a long period.

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## **ATTACHMENT B**









































## **ATTACHMENT C**



Aesculap AG  
Forschung und Entwicklung  
Postfach 40  
78501 Tuttlingen  
Deutschland

To whom it may concern

March 01, 2013

**Rationale regarding the comparison of the coated and uncoated CeSPACE with the test results of the AEscULAP® CeSPACE XP implant vs. AEscULAP® CeSPACE PEEK implant**

(b)(4) Test Data



Vorsitzender des Aufsichtsrates:  
Prof. Dr. h.c. Ludwig Georg Braun

Vorstand:  
Prof. Dr. Hanns-Peter Knaebel  
(Vorsitzender)  
Dr. Harald Stallforth  
(stellv. Vorsitzender)  
Dr. Joachim Schulz

Sitz der Gesellschaft: Tuttlingen  
Reg. Gericht: Stuttgart HRB 726261  
USt. Id.-Nr. DE812160059  
WEEE-Reg.-Nr. DE 65109852

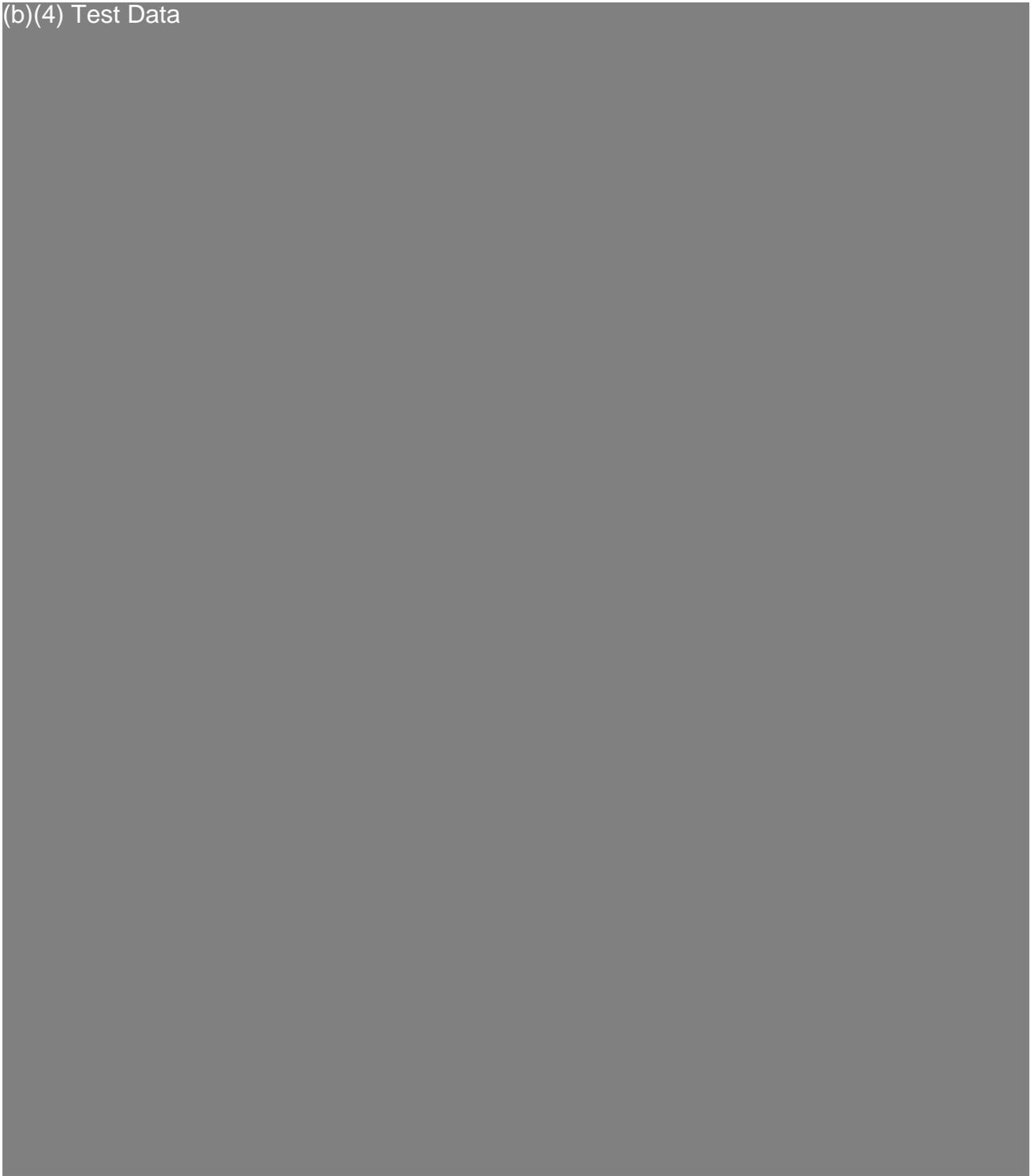
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SWIFT CODE: SOLA DE ST

Hausanschrift:  
Aesculap AG  
Am Aesculap-Platz  
78532 Tuttlingen  
Deutschland



Seite 2 zum Schreiben vom 2013-03-01 an

(b)(4) Test Data



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Seite 3 zum Schreiben vom 2013-03-01 an

(b)(4) Test Data



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Seite 4 zum Schreiben vom 2013-03-01 an

### Summary

The test results show that in comparison between the coated and uncoated CeSPACE PEEK the values are only slightly different. Additional investigation of the influence of the coating on the Peek was already performed. See investigation Report No. 10173.

Yours sincerely,

Aesculap AG

i.V.

PD Dr. Dr. Thomas Grupp  
Director  
R&D Knee Arthroplasty/ Biomechanical Research

i.A.

Dipl.-Ing. Christoph Schilling  
Research Engineer  
R&D Biomechanical Research

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## **ATTACHMENT D**



Aesculap AG  
Forschung und Entwicklung

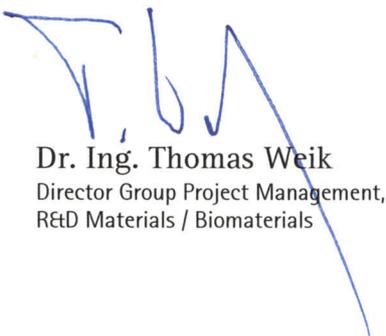
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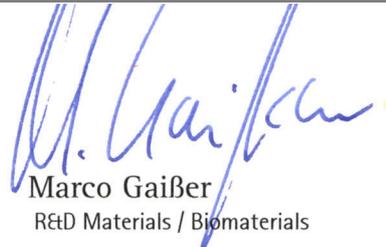
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**Rationale regarding the long-term stability of the Plasmapore XP coating**

(b)(4) Test Data



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# **ATTACHMENT E**

## **Aesculap CeSpace PEEK Spinal Implant System: Instructions for Use**

### **Indications for use:**

#### *When used as a Vertebral Body Replacement Device:*

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

#### *When used as an Intervertebral Body Fusion System:*

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

### **Materials**

The CeSpace PEEK Intervertebral Body Fusion System is manufactured from PEEK Optima LT1 (per ASTM F2026) with a titanium layer and a vacuum plasma spray coating (Plasmapore® - per ISO 5832-3), and contains Tantalum markers per ASTM F-560.

PEEK-OPTIMA® is a registered trademark of Invivo Ltd, Lancashire, FY5 4QD, UK.

### **General Surgical Indications**

Surgically installed implants serve to support normal healing processes. They should neither replace normal structures of the body nor permanently bear the loads occurring in the case of incomplete healing.

### **Contraindications**

The operation should not be carried out against the following contraindications:

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the PEEK devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses

- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient
- All cases that are not listed under indications

### **Risks**

The surgical intervention involves the following potential risks:

- Neurological complications caused by over distraction or trauma of the nerve roots or dura
- Loss of intervertebral disk height due to removal of healthy bone material

Complications that can generally occur in connection with intervertebral surgery:

- Pseudarthrosis
- Incorrect implant position
- Spondylolisthesis
- Loss of fixation; dislocation or migration

### **Side-effects and adverse interactions**

None known.

### **Safety notes**

- It is the operating surgeon's responsibility to ensure that the surgical procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present documentation.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be thoroughly familiar with bone anatomy, including the pathways of nerves, blood vessels, muscles and tendons.
- Aesculap is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- The instructions for use of the individual Aesculap implant components must be observed.
- Do not use damaged or surgically excised components under any circumstances.
- Implants that have already been used must not be reused.
- Delayed healing can result in implant rupture due to material fatigue.
- The implant components are supplied with their article numbers, the name of the implant, as well as the batch number and serial number (if applicable) which should be documented in all patient records.
- During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed.

### **Sterility**

- The implant components come individually packed in protective packaging that is labeled according to its contents.
- The implant components have been sterilized by irradiation (min. dose 25 kGy).
- Store implant components in their original packaging. Remove them from their original protective packaging only just prior to application.
- Prior to use, check the product expiry date and verify the integrity of the sterile packaging. Do not use implant components that are past their expiry date or if the package is damaged.

### **Application**

The operating surgeon draws up an operating plan that specifies and appropriately documents the following steps:

- Selection of the implant components and their dimensions
  - Positioning of the implant components in the bone
  - Location of intraoperative landmarks
- The following conditions must be fulfilled prior to application:
- All requisite implant components are ready to hand
  - Operating conditions are highly aseptic
  - The implantation instruments, including the special Aesculap implant system instruments, are complete and in working condition.
  - The operating surgeon and operating team are aware of information concerning the operating technique and the range of implants and associated instruments; this information is complete and ready to hand.
  - The operating surgeon is familiar with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific publications by medical authors.
  - The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.

The intervention has been explained to the patient, whose consent concerning the following information has been documented:

- In the case of delayed or incomplete fusion, the implants can break and loosen due to high loads.
- The life-span of the implant depends on the patient's body weight.
- Corrective surgery may become necessary if the implant loosens.
- The patient must undergo regular check-ups of the implant components, performed by a physician.

### **Implanting the PEEK devices**

- Select the appropriate PEEK implant size and shape according to the indication, the preoperative planning, and the bone situation found intraoperatively.
- Correctly apply the preparation instruments (rasps, curettes and chisels) for preparing the implant bed, as well as the implantation instrument.
- Apply appropriate care when inserting the implant.
- Check implant height and/or angle using the trial implants.

Further information on B. Braun/Aesculap implant systems is always available from B. Braun/Aesculap or the relevant B. Braun/Aesculap agency.

### **WARNING**

Implants supplied in sterile condition must not be resterilized or reused under any circumstances. Danger to the patient and possible loss of implant functionality due to resterilization!

### **WARNING**

Increased risk of migration due to over-preparation of the vertebral body endplates!  
When preparing the implant bed, make certain that the base and cover plates of the adjacent vertebral bodies are not weakened.

## **WARNINGS**

Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union) fracture of the vertebra, neurological injury, and vascular or visceral injury.

## **CAUTION**

Damage to the implant thread!

- Keep to the thread axis when screwing the implant onto the insertion instrument.
- Screw in the implant as far as it will go so that the dihedron of the instrument rests in the groove on the implant.

## **CAUTION**

Based upon dynamic testing results physicians should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the CeSpace implant when used as an intervertebral body fusion device.

## **PRECAUTION**

The CeSpace PEEK Spinal Implant System has not been evaluated for safety and compatibility in the MR environment. The CeSpace PEEK Spinal Implant System has not been tested for heating or migration in the MR environment.

## **Additional Information**

Please refer to the system's surgical technique for detailed implantation/explantation of information. To obtain a surgical technique guide, please contact Aesculap Implant Systems Customer Service Department at (866) 229-3002 or your Sales Representative.

## **Distributed in the U.S. by:**

Aesculap Implant Systems, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034

Phone: 800-234-9179

**Caution: United States (Federal) law restricts these devices to sale by or on the order of a physician.**

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