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Weissburg Associates
808 Williamson Street, Suite 402
Madison, Wisconsin 53703 USA
(b) (6) [redacted]

July 12, 2016

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

Attn: Submission Issue Q-Sub Guidance Request
Neurodiagnostic and Neurosurgical Devices Branch
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Ref: Submission Issue Q-Sub for K161090, OSSDSIGN Cranial PSI

The eCopy is an exact duplicate of the paper copy

CC via email: Gregg.Kittlesen@fda.hhs.gov, reviewer of K161090

Dear Sir or Madam,

Thank you for considering this Submission Issue guidance request for the OSSDSIGN Cranial PSI (K161090) which is currently on 180 day FDA hold. This Q-Sub conveys questions regarding several of FDA listed deficiencies in your 17Jun16 letter.

I request FDA's response in two forms:

1. I request a written response on the questions I pose in this Submission Issue Q-Sub as soon as possible, but not later than 3Aug16.
2. I request an informal telephone discussion with Dr. Kittlesen five days following FDA's written response.

Per (21 CFR 807.95), OSSDSIGN requests that this submission and the subsequent written communication with FDA be held in confidence by FDA and not distributed to any third party. We request that this restriction be applied to the maximum extent possible but with exceptions necessary to enable FDA to meet its statutory requirements.

Thank you for your consideration,

(b) (6) [redacted]

David Wei

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

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2. TABLE OF CONTENTS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12Jul16	Submission Issue Pre-Sub, fee not applicable	K161090

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☒ Other *(specify):* *Submissoin Issue Q-Sub*
	☐ Other			

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
OssDsign AB			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	+46 (0) 18-55 39 93		
Street Address	**FAX Number *(including area code)***		
Virdings Alle 2	ub@ossdsign.com		
City	**State / Province**	**ZIP/Postal Code**	**Country**
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Contact Name			
Ulrik Birgersson			
Contact Title	**Contact E-mail Address**		
Director Clinical Engineering	ub@ossdsign.com		

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

Company / Institution Name			
Weissburg Associates			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(b) (6)		
Street Address	**FAX Number *(including area code)***		
808 Williamson St., Suite 402	(b) (6)		
City	**State / Province**	**ZIP Code**	**Country**
Madison	Wisconsin	53703	USA
Contact Name			
David Weissburg			
Contact Title	**Contact E-mail Address**		
Principal	(b) (6)		

OssDsign Confidential

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

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

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

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

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

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

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

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

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

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

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

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

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

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

- [ ] Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

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

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

This Submission Issue Q-Sub pertains to Deficiency List items noted by FDA in its substantive response to K161090, dated 17Jun16.

FORM FDA 3514 (1/13)

Records processed under FOIA Request 2024-2037, released by CDRH on 02-20-2024, re-released 03-31-2024 by CDRH under 2024-6423.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GXN	2	GXR	3	MAX	4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K062570 (predicate, same titanium material and mechanical performance)	1	Patient Contoured Mesh (PCM), Plate, Cranioplasty, Preformed, Non-Alterable	1	KLS-MARTIN L.P
2	K140309 (reference device, same titanium and calcium phosphate materials)	2	Cranioplug, Burr Hole Cover	2	OSSDSIGN
3	K141405 (reference device, same additive manufacturing process, same titanium material)	3	Mobis II ST Spinal Implant	3	Signus Medizintechnik
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Plate, Cranioplasty, Preformed, Non-Alterable (Patient-specific Implant made of Ti, PEEK or PMMA) (21CFR882.5330)

	Trade or Proprietary or Model Name for This Device		Model Number
1	OSSDSIGN Cranial PSI	1	patient-specific design
2		2	
3		3	
4		4	
5		5	

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

1 Q130597	2 K140309	3 Q150051	4 K160452	5 Q150051-S001	6 K161090
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	C.F.R. Section *(if applicable)*	Device Class
GXN	21CFR882.5330	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification Panel		
Neurology		

Indications *(from labeling)*

OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: OssDsign AB		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: +46 (0) 18-55 39 93	
Street Address: Virdings Alle 2		FAX Number *(including area code)*: ub@ossdsign.com	
City: Uppsala	State / Province	ZIP Code: SE 754 50	Country: Sweden
Contact Name: Ulrik Birgersson	Contact Title: Clinical Engineering Director	Contact E-mail Address: ub@ossdsign.com	

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

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

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

Records processed under FOIA Request # 2017-1437 released by CDRH on 03-21-2024 Re-released 10-31-2024 by CDRH under 2024-6423.

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	ISO 10993-1	ISO	Biological evaluation of medical devices.	2009	01/01/2009
2					
3					
4					
5					
6					
7					

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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4. BACKGROUND

OSSDSIGN is a Swedish medical device company founded in 2011 which designs and manufacturers titanium + calcium phosphate implants.

The OSSDSIGN Cranial PSI (Patient Specific Implant) is a custom cranioplasty device that replaces native bone in the cranial skeleton. Each Cranial PSI is a custom made device specifically created for a patient's unique anatomical requirements. As of 14Apr16, Cranial PSI devices have been implanted in (b) (4) patients. A premarket submission for this device has been filed (K161090) and is currently on 180-day hold pending additional information.

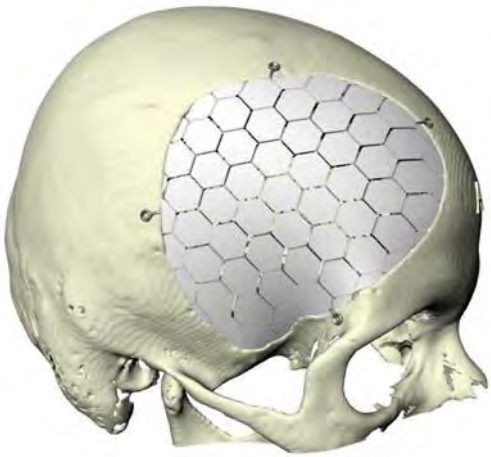


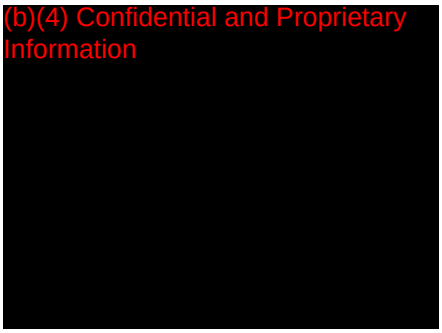
Figure 1. Cranial PSI

KEY ISSUE – OSSDSIGN has elected to remove certain claims from our Cranial PSI submission (K161090), and to add certain restrictions. These changes resolve many of FDA's noted deficiencies and are fundamental background to the context of our questions in Section 8 of this Q-Sub.

(b)(4) Confidential and Proprietary Information

[redacted]

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.



Claims/restrictions to be added:

7. "Intended for use with an intact dura, with or without duraplasty"
    a. This is how the device is currently used.
    b. This should clarify that there is minimal blood/CSF contact and no blood/CSF communication from the device back to the inside of the dura.

8. "12 month shelf life"
    a. Clarified shelf life/sterility and performance testing will be provided

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5. DEVICE DESCRIPTION

Cranial PSI consists of a titanium mesh that is largely covered by ceramic tiles. The titanium mesh provides mechanical stability. The ceramic tiles provide favorable cosmetic outcome by more naturally following the curvature of the skull. The implants are designed in a mosaic pattern with space between tiles that allows for free circulation of blood and fluids. For further information, see (b) (4) - Product Specification Cranial PSI, on page 52 of our premarket submission.

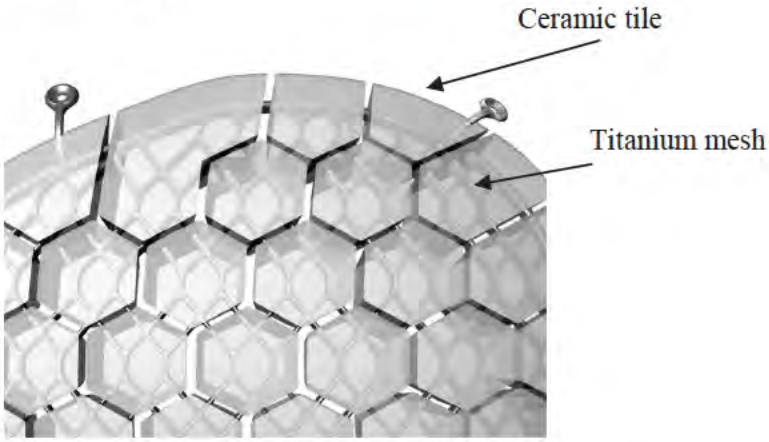

Figure 2. Section of Cranial PSI, top view. Ceramic tiles have been made transparent in the image to show the titanium mesh embedded within the tiles.

Figure 3. Cranial PSI side view.
Ceramic tile thickness: 6 mm.
Titanium mesh thickness: 1.6 mm.

Figures 2. and 3. show a conceptual design of sections of a typical Cranial PSI. Standard 3mm or 4mm titanium surgical screws, such as Medicon Ti Micro 1.5x 4.0, are used to fasten individual Cranial PSI devices to the skull. Screws are not provided with the Cranial PSI.

The size and shape of each Cranial PSI is determined based on each patient's unique x-ray computed tomography (CT) scan submitted to OSSDSIGN by the ordering surgeon. Cranial PSI is delivered sterile.

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

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Material Description

KEY ISSUE - Cranial PSI is made from additively manufactured Ti6AI4V titanium and IDA3 calcium phosphate ceramic. **Both materials and their manufacturing processes are previously cleared by FDA**.

Titanium: The additively manufacture titanium used in the Cranial PSI is i(b) (4) to Signus Medizintechnik's Mobis II ST Spinal Implant (K141405). This reference device was noted on page 159 of our premarket submission, but I believe was not sufficiently highlighted. Both devices use titanium alloy Ti6AI4V, Grade 23 (ASTM F136). (b) (4)

(b)(4) Confidential and Proprietary Information

(b) (4)

Manufacturing and Biocompatibility Report starts on page 144 of our premarket submission and the Cleaning Validation Report is provided in (b) (4)

(b) (4)

Calcium Phosphate Ceramic: OSSDSIGN's proprietary IDA3 ceramic used in Cranial PSI is **identical** to OSSDSIGN's cleared Cranioplug (K140309, burr hole cover). Both devices are manufactured, cleaned and sterilized with the same process by OSSDSIGN.

Clinical Experience

From its introduction in 2014, Cranial PSI has been used clinically in over (b) patients with various cranial defects. Cranial PSI's predecessor, Craniomosaic, received a registration certificate on July 10, 2012 from the Swedish Medical Product Agency as a custom-made device. It has been used clinically under this registration certificate since October 2012, for further information see (b) (4) - Cranial PSI Clinical Use, on page 432 of our premarket submission.

References

(b)(4) Confidential and Proprietary Information

(b) (4)

- IDA3 Specification
- Cranial PSI Clinical Use
- Product Specification Cranial PSI

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

6. INDICATIONS FOR USE

OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete *and for use with an intact dura, with or without duraplasty*.

The text in *italics* is a proposed additional clarification.

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

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

7. PREVIOUS SUBMISSIONS

Guidance request Q130597 was submitted by OSSDSIGN and guidance was received from FDA. This Q-submission pertained primarily to an earlier version of Cranial PSI (*Craniomosaic*), which OSSDSIGN no longer produces and which will not be introduced into the USA market. The Cranial PSI device currently under review (K161090) is additively manufactured by 3D printing the titanium mesh to each patient's specific requirements. Weld joints originally specified in Q130597 are no longer used.

Cranioplug001 premarket submission (K140309) was reviewed and cleared by FDA's Gregg Kittlesen, PhD. This device has the identical ceramic materials, ceramic manufacturing process and sterilization procedure as the current device Cranial PSI.

(b)(4) Confidential and Proprietary Information

[redacted]

FDA's initial Q150051 guidance was communicated in a 6May15 letter. This guidance included an initial recommendation for a calvarial implant study of a relevant sized defect.

A guidance meeting was held at FDA on 7May15 to review Q150051. All parties learned that FDA's guidance was based several incorrect assumptions about Cranial PSI which OSSDSIGN had not adequately described in its Q-Sub. A central issue was that the cleared device Cranioplug (K140309) was made of identical ceramic materials and ceramic manufacturing process as Cranial PSI. The parties also discussed that there is no *in vivo* calvarian study of a relevant sized defect that can effectively model the subject device for its intended use, and that FDA's principal aim of such a study was to confirm effects of any leaching materials. The parties agreed OSSDSIGN would submit a supplemental Q-Sub to clarify important facts and provide further information. The information to be provided would include:

A. Relevant pages of the Cranioplug premarket submission (K140309) which describes the ceramic molding process,
B. A side-by-side comparison summary of the materials and methods used in Cranioplug and Craniomosaic production,
C. Flow charts of the Cranioplug and Craniomosaic manufacturing processes, including chemicals used,
D. Testing plan for methods and materials of the new 3D printed titanium mesh introduced with Craniomosaic,
E. Implant testing plan, if any, or justification for omitting a second implantation test.

OSSDSIGN submitted Q150051 Amendment #1 Draft Meeting Minutes on 18May15.

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OSSDSIGN submitted Q150051-S001 Supplemental Guidance Request on 3Sep15. This submission pertained to two issues in the Cranial PSI premarket submission (K161090) which have been noted as deficiencies by FDA:

A. OSSDSIGN's revised biocompatibility testing plan (Q150051-S001 question 3.) and
B. OSSDSIGN's justification for using "further well controlled (bench) studies" and not an "*in vivo* test of relevant sized defect (calvarial study)" (Q150051-S001 question 4.)

(b)(4) Confidential and Proprietary Information [redacted]

FDA responded to OSSDSIGN's 18May15 Amendment #1 Meeting Minutes and 3Sep15 Q150051-S001 Supplemental Guidance Request on 18Feb16 (b)(4) Confidential and Proprietary Information [redacted]

(b) (4) [redacted]

A. Regarding our biocompatibility testing plan (question 3.), FDA stated that OSSDSIGN may be "***able to leverage your Cranioplug biocompatibility data if you are able to demonstrate that there are either no residuals or that residuals extracted are no different toxicologically than the residuals of the predicate or reference device.***"

This path was guided subject to favorable completion of specific chemical and bench studies, and as FDA noted in its K161090 Deficiency List, several items of the exhaustive extraction analysis remain to be completed.

B. Regarding our proposed use of further well controlled (bench) studies, and <u>not</u> a calvarial study (our questions 4.), FDA stated that: "***We believe upon satisfactory performance of the dynamic load, resistance to deformation, and max load capacity testing, that these tests satisfy our guidance for further well-controlled studies.***"

FDA removed its prior guidance for a calvarial study.

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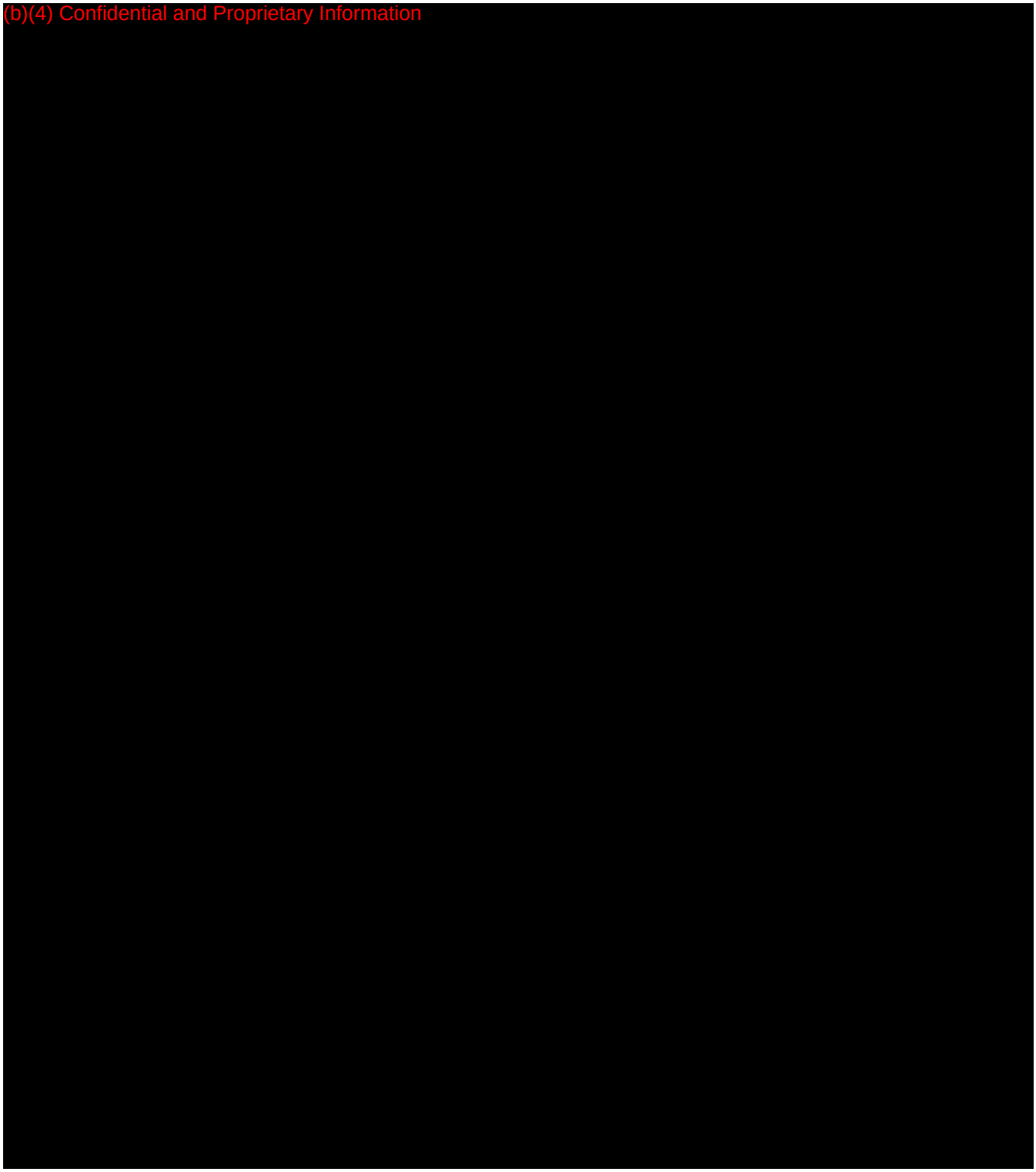
8. SPECIFIC QUESTIONS

(b)(4) Confidential and Proprietary Information



Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

(b)(4) Confidential and Proprietary Information

[redacted]

OSSDSIGN will submit an updated chemical residuals analysis with exhaustive extraction on the "worst case" final, sterilized Cranial PSI device that shows conformance to requirements for residual amounts and sizes.

Q1: Does this explanation of (b) (4) answer FDA's concerns or is there some other aspect of (b) (4) " that has drawn FDA concern?

2. Blood/CSF Classification <FDA Deficiency List item 12>:

Cranial PSI is "Intended for use with an intact dura, with or without duraplasty". Standard clinical practice in neurosurgery is to seal the dura water-tight prior reposition of autologous bone or by using an implant of any cranioplasty device, including Cranial PSI. We note that Cranial PSI allows for "free circulation of blood and fluids", however Cranial PSI allows for free transfer of ***tissue fluids*** from the extradural space and does not contribute to fluid buildup in the dead-space between the dura and the implant.

This is how the device is currently used in Europe and the named restriction to use with an intact dura was not clear in our premarket submission. We have added labeling to our Indications For Use to include the restriction that Cranial PSI is *for use with an intact dura, with or without duraplasty*.

Despite a watertight duraplasty, there is the possibility of CSF leakage from inside the dura to outside the dura until the dura healing process is complete. Our device may contact incidental amounts of extradural blood/CSF and this fluid can transfer through the Cranial PSI and be absorbed by soft tissue or drained by extra-cranial drainage.

OSSDSIGN maintains a rigorous field surveillance program which shows Cranial PSI has lower side effects that alternative devices and autografts. No device adverse events due to fever or rejection have been reported in the European clinical cases. For further information see (b) (4) Cranial PSI Clinical Use, page 432 of our premarket submission.

Rationale that further biocompatibility testing is not indicated includes:

A. Successful completion of: sensitization, two sensitivity an (b) (4) subcutaneous implantation studies

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

B. The pending, updated chemical residuals analysis with exhaustive extraction on the "worst case" final, sterilized Cranial PSI device that will show compliance with requirements
C. Prior FDA clearance of the (b) (4) materials, manufacturing processes and manufacturing residues:
    i. Mobis II ST Spinal Implant (K141405) has (b) (4) titanium alloy materials and additive manufacturing process as the titanium mesh in Cranial PSI
    ii. Cranioplug (K140309) has identical IDA3 ceramic materials, manufacturing process of molding the ceramic to the titanium and the same manufacturing residuals
D. Absence of adverse device events related to biocompatibility in over 84 European cases. See (b) (4) - Cranial PSI Clinical Use on page 432 of our premarket submission.
E. Titanium and Calcium Phosphate are very well understood, benign materials used in hundreds of regulated products
F. Absence of FDA feedback stating a blood contact designation or request for these specific tests in FDA's guidance Q150051 and Q150051-S001.

Q2a: Does FDA agree that our device in not blood/CSF contacting and should be classified as Tissue/Bone contacting?

Q2b: OSSDSIGN would agree to add a warning that a surgical drain should be used if blood/CSF leakage is expected. This is standard clinical practice. Would FDA favor this warning?

Q2c: OSSDSIGN asks FDA to consider one of three proposed solutions:

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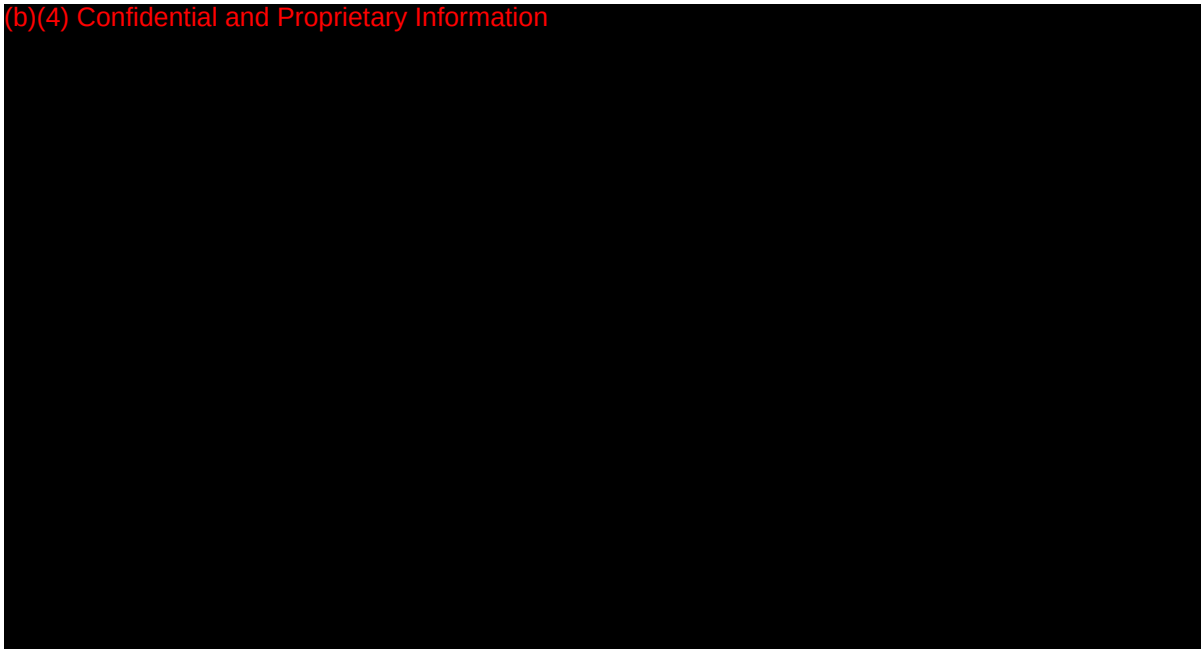

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3. Implantation Study <FDA Deficiency List item 13b>:
   A chronology of events has evolved regarding the FDA's assessment of need for a calvarial implantation study.
   A. This study was initially recommended by FDA in its guidance Q150051
   B. During the FDA/OSSDSIGN 7May15 meeting, it became clear that some FDA assumptions about our materials and manufacturing method that led to this recommendation were incorrect and FDA suggested that OSSDSIGN provide more clarifying information.
   C. We submitted Q150051-S001, providing further clarification of why this study was not justified given:
      i. Well understood and previously cleared materials,
      ii. Lower clinical side effects reported in Europe, and
      iii. Clean results from all biocompatibility studies, including our (b) (4) (b) (4) implantation studies.

      In Q150051-S001 we asked FDA if, in light of this further information, FDA would accept our revised biocompatibility testing plan which excluded a calvarian implantation study.
   D. In FDA's response to Q150051-S001, the implantation study guidance was removed
   E. We have now taken further steps to lower potential or perception of risk, including:

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      vi. Added the additional indication for use that the device is intended for *"use with an intact dura, with or without duraplasty"*
      vii. Will provide an updated chemical residuals analysis consistent with FDA's item 13a which confirms conforming results
   F. We have clarified that Cranial PSI's two materials and their associated manufacturing processes have already been cleared by FDA.
      i. Cranial PSI's titanium mesh and Mobis II Spinal Implant (K141405) are both additively manufactured of Ti6Al4V titanium (b) (4)

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      ii. Cranial PSI's IDA3 calcium phosphate ceramic and the ceramic portion of the Cranioplug (K140309) both have identical materials and manufacturing processes, and are produced by OSSDSIGN in its Uppsala, Sweden facility.

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Q3a: Has this additional and clarified information, the removal of some claims and the addition of some restrictions satisfied FDA's renewed interest in an additional implantation study?

Q3b: If not, on what basis has FDA made its determination to re-introduced the requirement for this test after guidance to the contrary, and after the further lowering of risk by OSSDSIGN?

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9. METHOD OF FEEDBACK

I request FDA's response in two forms:

1. I request a written response on the questions I pose in this Submission Issue Q-Sub as soon as possible, as OSSDSIGN is under a response deadline to provide additional information to FDA for K161090.
2. I request an informal telephone discussion with Dr. Kittlesen five days following FDA's written response.

Respectfully submitted,

(b) (6) [redacted]

David Weissburg

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510(k) SUMMARY

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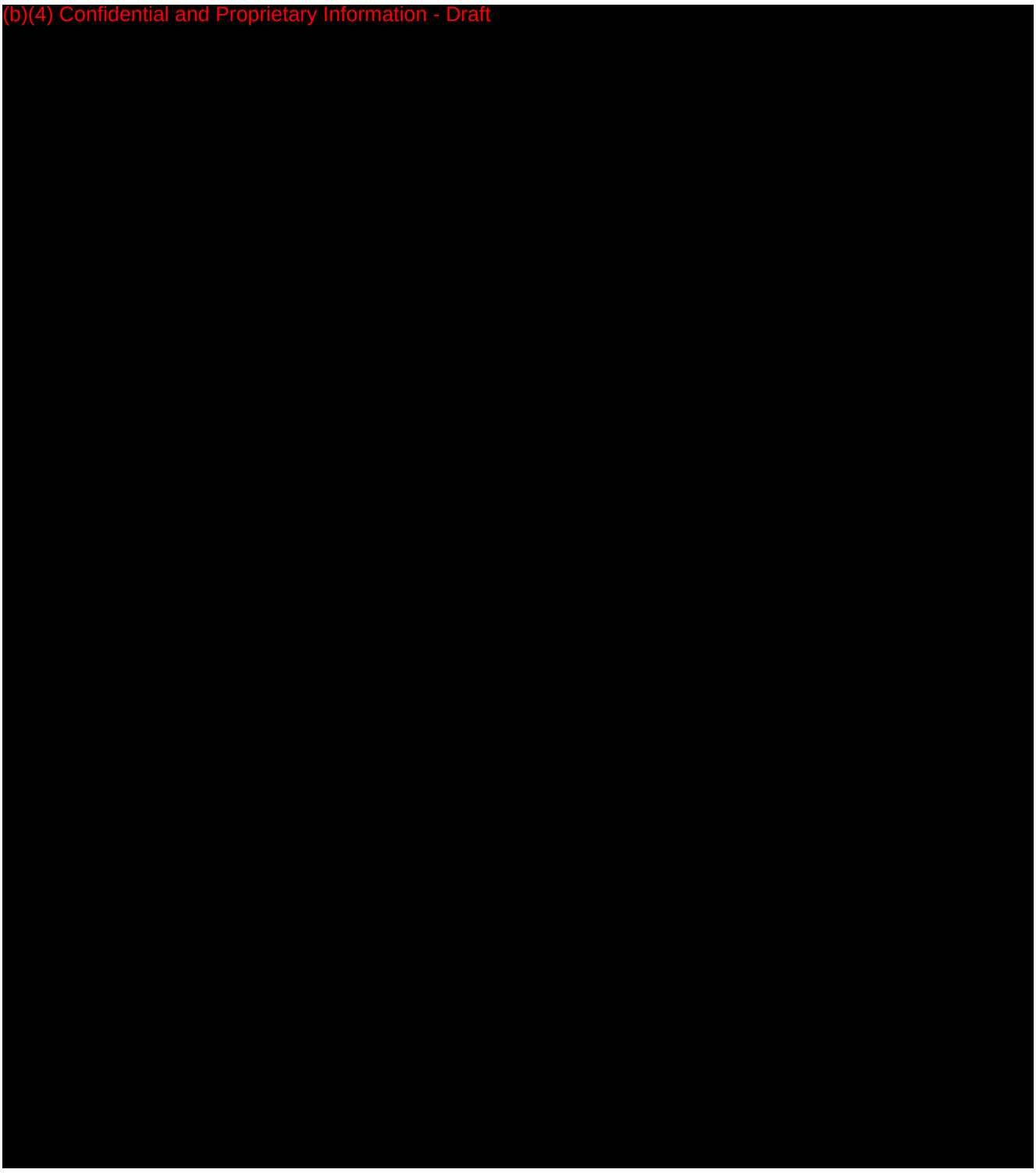

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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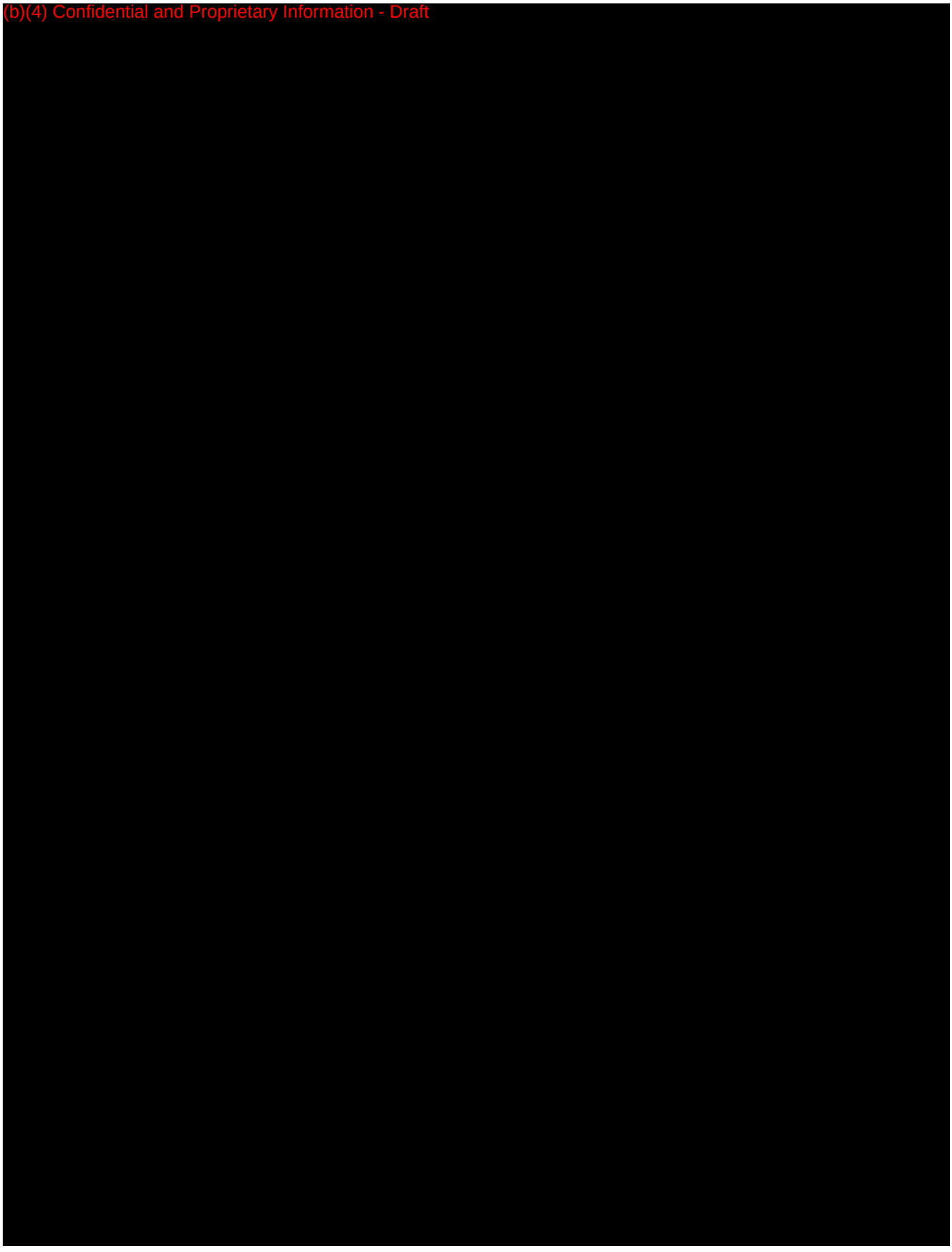

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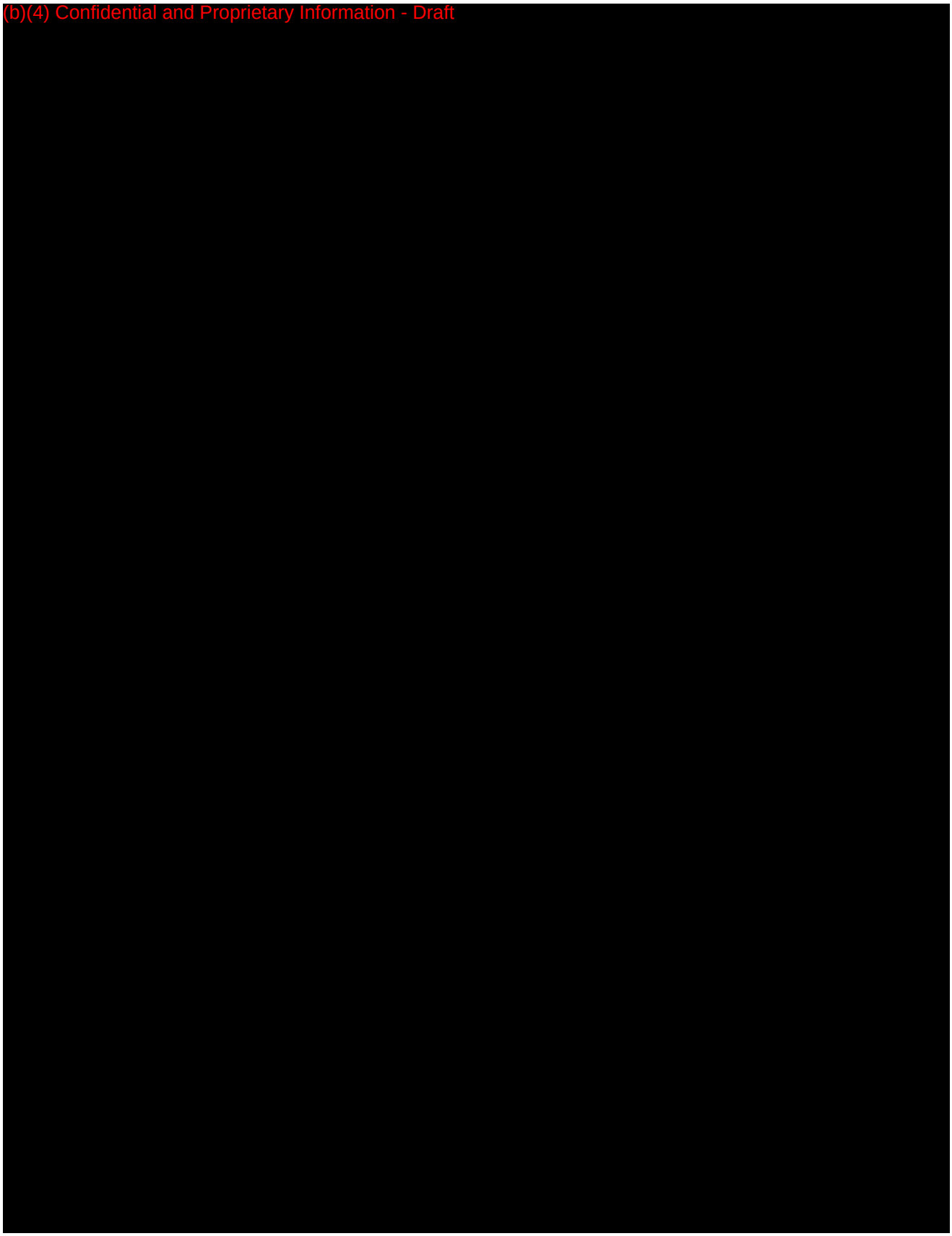

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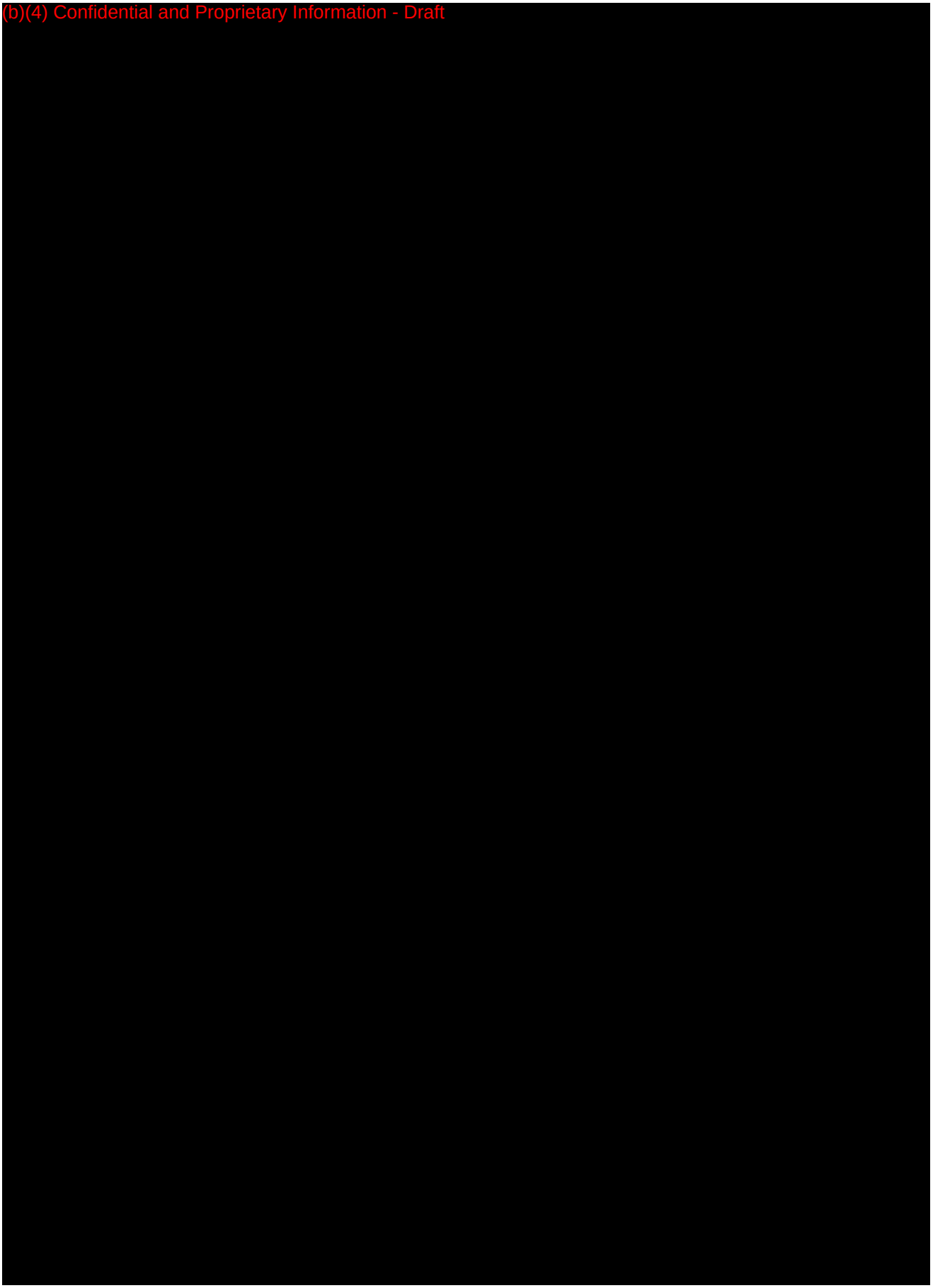

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Hello Dr. Kittlesen,

Attached is draft v4 3 of the 510(k) Summary in redline and blackline. This version reflects my understanding of the points in our discussion this morning.

I look forward to talking with you further at 11a EST today.

Thank you,

David Weissburg
Weissburg Associates
(b) (6)

WeissburgAssociates.com

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

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Cranial PSI Resistance to Deformation Test Protocol

Purpose of Test

To establish the deformation of the device from an external load of 100N.

Articles to be Tested

To be indicated in test protocol, including lot number or other identification.

Materials/Equipment

Article	Manufacturer
Test fixture, PLA. Anatomical model of defect contour of the device to be tested, see Fig 1.	OssDsign
Screws	Brand, article and lot number to be noted in test report
10 mm ø PLA cylinder, height 10 mm.	OssDsign
Universal testing machine	Shimadzu

Method

Prior to testing, the testing point on the device is identified in the device drawing. Using the software Rhinoceros, all tiles are selected and the gumball marker is aligned to the object(s). This will automatically place the gumball marker at the gravitational center of the selected object(s). Use an ink pen to prominently mark on the finished device the ceramic tile closest to the position indicated by the Rhinoceros gumball marker. This is the positioning point for the test.

Attach the implant to the anatomical model using the number of screws indicated in manufacturer's instructions. Place the anatomical model against a neutral background and take before image(s) showing device curvature and position of the center tile.

Place the anatomical model in the Universal Testing Machine (UTM). Place the cylinder on the tile marked as the positioning point. Lower the UTM cross head until it is in direct contact with the cylinder. Set distance to "zero" at this position. Set the machine to press with a constant speed of 1 mm/min until it has reached a force of 100 N. When the force has been reached and the test stops slowly raise the cross head until the force is zero. Record the distance at this point to establish plastic deformation.

Place the anatomical model with device against a neutral background and take after image. If the device has reached failure take image of point/s of failure.

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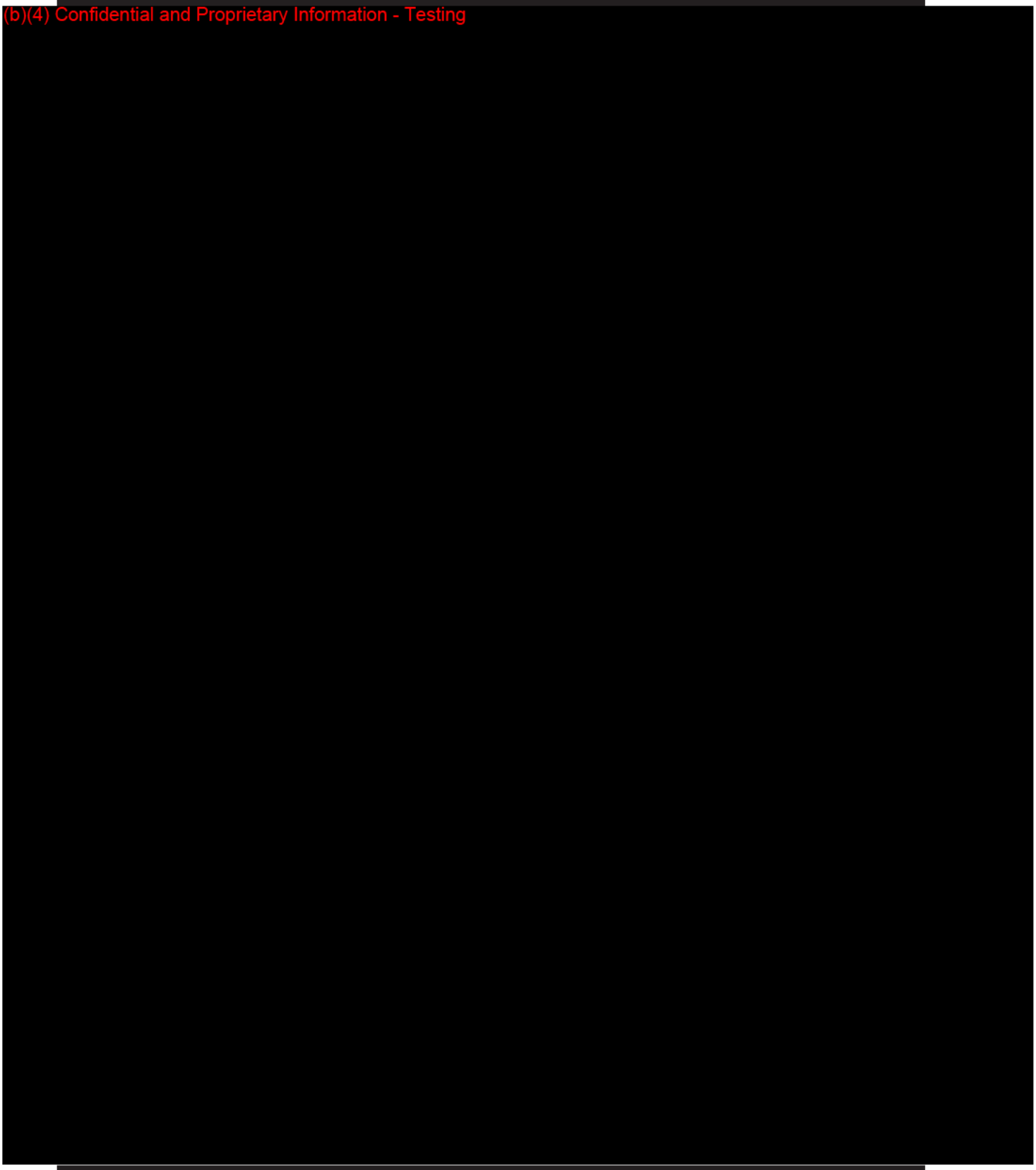

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Dear Mr. Weissburg,

Thank you for your phone call today.

We are within a few days of our substantive interaction. Therefore, it would not be appropriate at this time to send additional information.

Best regards,

Gregg Kittlesen, Ph.D.
Materials Engineer
CDRH/ODE/DNPMD/NNDB
WO66 - 2615

tel: 301-796-6473

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https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=463&E=&S=E

The opinions expressed in this message represent the best judgment of the sender and do not necessarily represent the formal position of the FDA under 21 CFR §10.85

From: Cisco Unity Connection Messaging System [mailto:unityconnection@fdsla04029.fda.hhs.gov]
Sent: Friday, June 10, 2016 9:20 AM
To: gregg.kittlesen@fdsla04029.fda.hhs.gov
Subject: Message from Unknown sender (6087700223)

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510(k) SUMMARY

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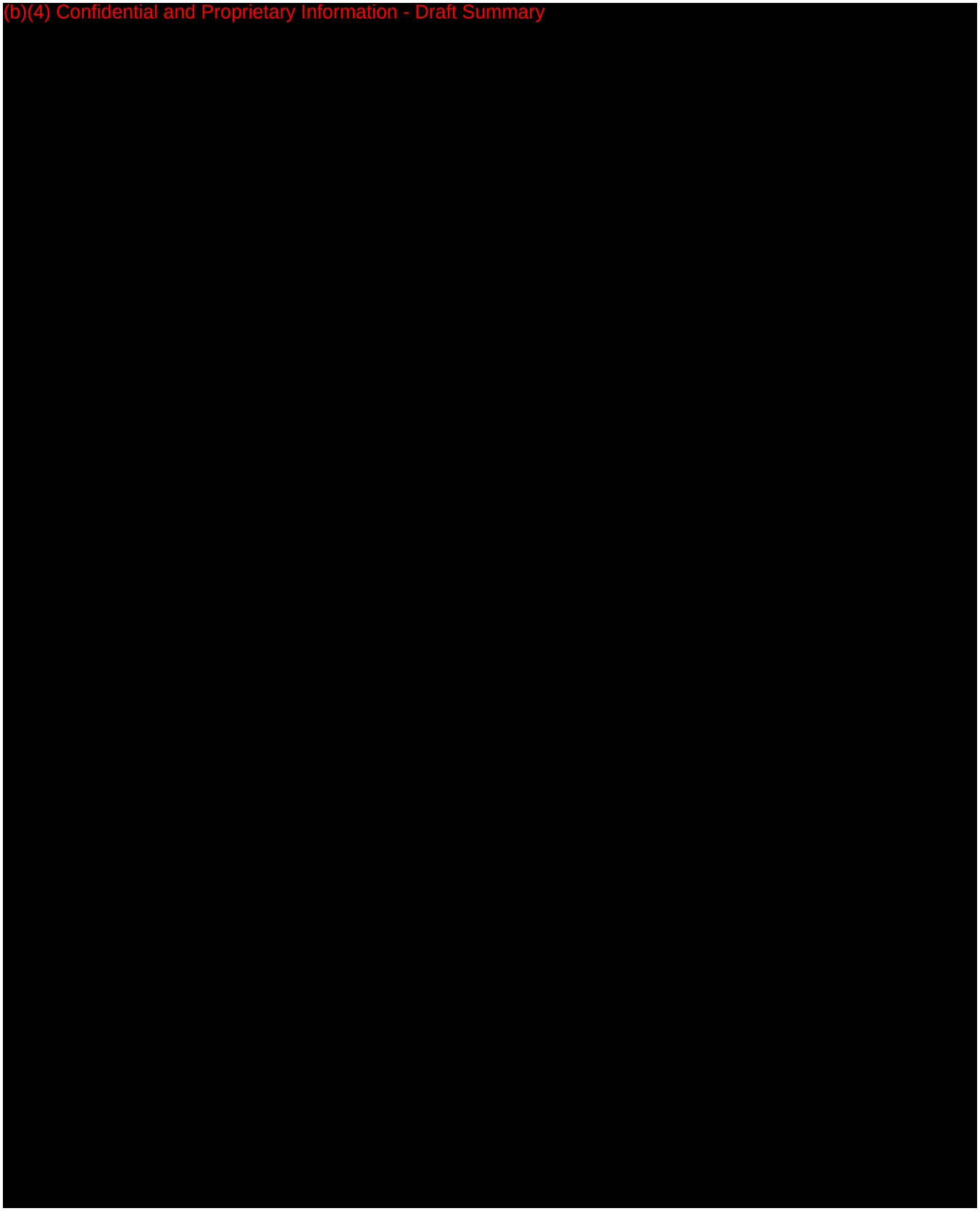

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[redacted]

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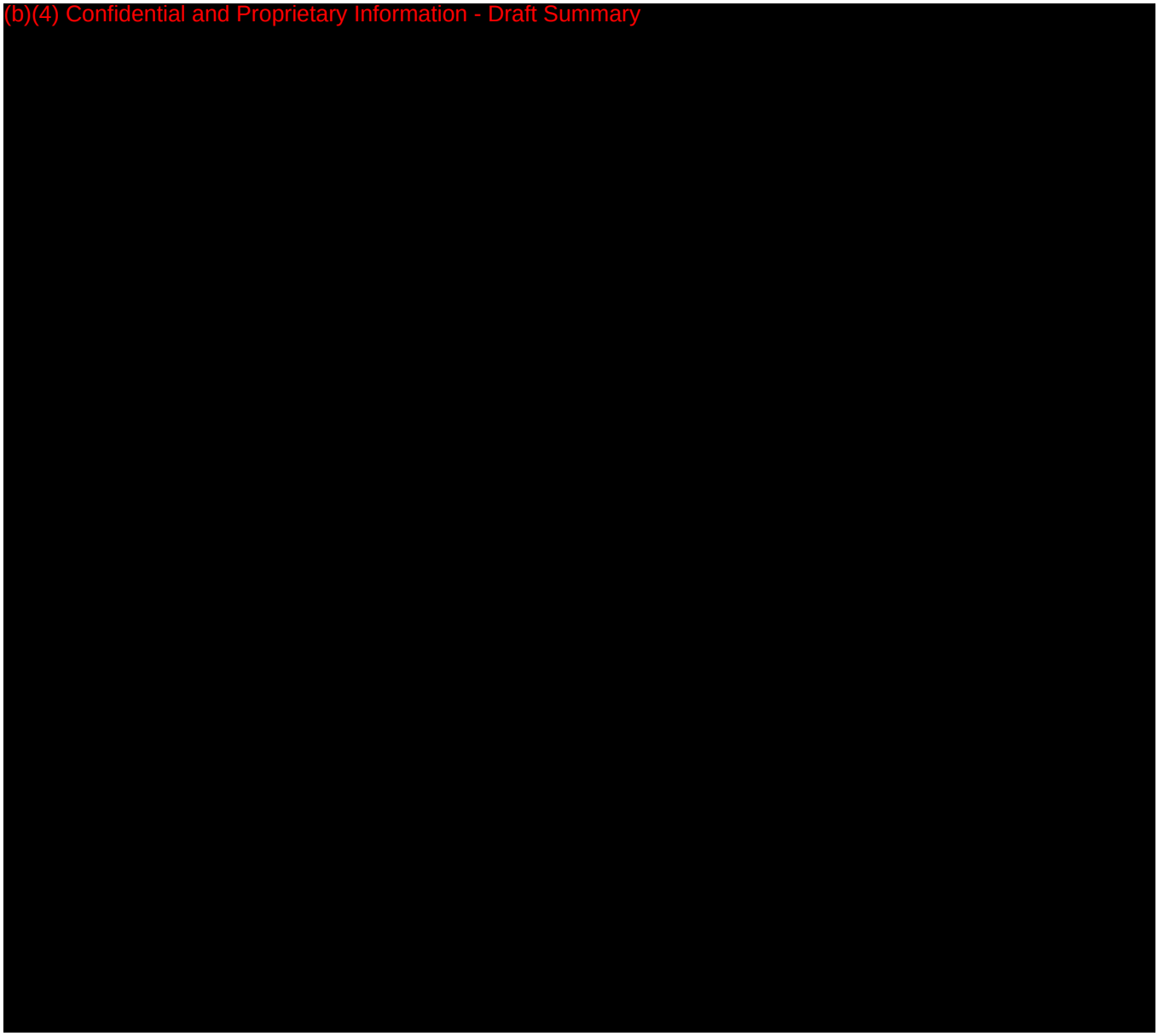

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510(k) SUMMARY

K161090

1. 510(k) Owner Name and Address:
   OSSDSIGN AB
   Virdings Alle 2,
   SE 754 50, Uppsala
   Sweden
   Telephone: +46 (0) 18-55 39 93
   Email: ub@ossdsign.com
   Contact: Ulrik Birgersson

2. Contact Person:
   David Weissburg
   Weissburg Associates
   808 Williamson St., Suite 402
   Madison, Wisconsin, 53703 USA

3. Date prepared: January 18, 2017

4. Trade Name: OSSDSIGN Cranial PSI

5. Regulation Description: Preformed Non-alterable Cranioplasty Plate

6. Classification Name: Plate, Preformed Non-alterable Cranioplasty Plate (21 CFR 882.5330, Product code: PJN)

7. Class: 2

8. Substantially equivalent to: KLS Martin – Patient Contoured Mesh (K062570)

9. Device Description: OSSDSIGN Cranial PSI (Patient Specific Implant) is a device that replaces native bone in the cranial skeleton. Each Cranial PSI is a patient-specific device specifically created for a patient's unique anatomical requirements. Cranial PSI consists of a rigid titanium mesh that is largely covered by biocompatible ceramic tiles. The ceramic tiles are in a mosaic pattern that provides space between tiles to allow free circulation of fluids.

10. Indications for Use: OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

11. Comparison of Technological Characteristics with the Predicate Device :

	OSSDSIGN Cranial PSI (K161090, subject device)	KLS Martin Patient Contoured Mesh (K062570, predicate)
Indications For Use	OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.	Patient Contoured Mesh (PCM) is intended to replace bony voids in mandibular, maxillofacial or craniofacial skeleton.
Materials	Ti grade 23, proprietary calcium phosphate ceramic	CP Titanium

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	OSSDSIGN Cranial PSI (K161090, subject device)	KLS Martin Patient Contoured Mesh (K062570, predicate)
Titanium thickness	0.4 – 1.6 mm	0.6 – 1.0 mm
Max size	200 cm^2	200 cm^2
Provided form	Titanium and Ceramic Ceramic mixed and cured in manufacturer's facility	Titanium only
Sterility on delivery	Sterile	Non-sterile

12. Testing vs. predicate:

Test Method and Relevance Summary	Results	
	OSSDSIGN Cranial PSI	KLS Martin - PCI Titanium Mesh (K062570)
	Size: 197 cm^2	Size: 197 cm2
Dynamical Load Test: To verify that the Cranial PSI supports the forces exerted onto the implant from sleeping during the device lifetime. Requirement: no deformation Method: orbital shaker, 125 rpm, 60 hours. Relevance: test simulates changed head position every 20 minutes during 8 hours sleep for 50 years. Both the subject device and predicate passed the test.	No deformation	No deformation
Max Force [N] To establish the maximum force that can be applied to the device before failure. Requirement: >100 N Method: Universal testing machine at 1 mm/min Relevance: protection from falling objects and blunt trauma. Both the subject device and predicate passed the test. The subject device provided moderately better performance than the predicate.	461	383
Energy absorption [mJ] To establish the maximum energy the device can absorb before failure. Requirement: >1000 mJ Method: Universal testing machine at 1 mm/min Relevance: protection from falling objects and blunt trauma. Both the subject device and	2260	3760

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predicate passed the test.		
Resistance to Deformation [mm] To establish device resistance to deformation before device failure. Requirement: <6 mm Method: Universal testing machine at 1 mm/min to 100 N applied force Relevance: Both the subject device and predicate passed the test.	0.5 mm	1.1 mm

13. Biocompatibility:

Test	Test Method Summary	Results
Cytotoxicity	ISO 10993-5 Method:L-929 mouse fibroblast cells	Not cytotoxic No evidence of causing cell lysis or toxicity
Sensitization	ISO 10993-10 Method: guinea pig maximization test	Non-sensitizer All test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
Sensitivity, Irritation	ISO 10993-6 Method: polar and non-polar test article extracts intracutaneously injected into five separate sites on the right side of the back of three rabbits. Observations for erythema and edema were conducted at 24, 48, and 72 hours.	Non-irritant Difference between the test and the control mean scores <1.0, confirming the device is a non-irritant
Systemic (acute) toxicity	ISO 10993-11 Method: 20 mice observed at 4, 24, 48 and 72 hours.	Non-toxic No mortality or evidence of systemic toxicity
Genotoxicity	ISO 10993-3 Method: mouse lymphoma forward gene mutation assay.	Not mutagenic <2-fold increase in mean mutant frequency of the L5178Y/TK cell line.
Mutagenicity	ISO-10993-3 Method: bacterial reverse mutation study	Non-mutagenic <2-fold increase in mutagenic frequency.
Implantation	ISO 10993-6 Test for local effects after implantation, 2- and 6-week subcutaneous implantations in rabbits.	Non-irritant Non-irritant compared to control.

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Analytical Extractable Chemical Analysis	ISO 10993-12 Analysis by GC-MS, ICP-MS, LC-MS and HPLC-ELSD	Non-hazardous in all results, including extractions in polar, non-polar and mid-polar solvents. No hazardous materials detected.
Indirect Hemolysis	ISO 10993-4 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	The hemolytic index for the test article extract was 3.8% and the test article extract was slightly hemolytic. All samples passed the acceptance criteria.
Material Mediated Pyrogenicity	ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, Pyrogen Test	The total rise of temperatures during the 3 hour observation period was within acceptable limits. The test article was judged as nonpyrogenic. All samples passed the acceptance criteria

14. Conclusions:

Nonclinical tests demonstrate that Cranial PSI is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified in this summary.

- Cranial PSI mechanical performance in a battery of life-style emulating test scenarios shows substantial equivalence in mechanical effectiveness compared to the predicate device
- Cranial PSI demonstrated biocompatibility per current consensus standards

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

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

K161090
OSSDSIGN AB
Device Trade Name: Cranial PSI
Contact Name: Mr. David Weissburg

DEFICIENCY LIST

Administrative Information

1. You provided brief phrases and values regarding "Testing vs. predicates" in your 510(k) Summary. However, your brief phrases and omission of biocompatibility are not sufficient for the 510(k) Summary and do not provide a high level summary of the tests and leveraged data that were used to demonstrate the substantial equivalence of your device. Therefore, please revise your 510(k) Summary to include a discussion of the bench tests, biocompatibility tests, animal study(ies), and published literature described in your submission for a determination of substantial equivalence (e.g., purpose, test conditions, acceptance criteria similar to predicate device testing, etc.). In addition, please include the specific conclusions drawn from your performance testing that demonstrate the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices. Please provide a red-lined and final clean copy (e.g., no section numbers, stand-alone document with its own set of page numbering) of your revised 510(k) Summary for our review. For guidance, please refer to the sample table below for your presentation of the performance testing in the 510(k) Summary:

Test	Test Method Summary	Results
Name of Test	Description of test apparatus, conditions, duration, etc. In addition, this section can discuss the purpose of each type of bench testing.	Discussion of results such as all samples passed the acceptance criteria and the relevancy of the test result in determining the substantial equivalence of the proposed device.

2. You referenced several consensus standards for validation of the moist heat sterilization process, for endotoxin testing and for leveraging package verification/shelf-life testing. However, you do not provide a separate "Standards Data Report for 510(k)s" (FDA Form 3654) for each referenced consensus standard. A completed FDA Form 3654 should be submitted for each standard which you use to establish the substantial equivalence of your device. Therefore, please submit a completed FDA Form 3654 for each consensus standard used in sterilization validation, endotoxin testing and in package verification/shelf-life testing, in which you identify and justify any deviations to a related FDA recognized consensus standard. FDA's database of currently recognized consensus standards is located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Labeling

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3. Your proposed Directions for Use (DFU) include some information that is unclear and that could lead to unsafe use of your device. Please provide red-lined and clean copies of your DFU that addresses the following concerns:

    a. You listed "Patients who are potentially non-compliant with after-procedure instructions" among the Contraindications. However, you do not provide after-procedure instructions in your labeling as these instructions are particularly important for the safety of the patients that are implanted with large ceramic cranial implants. Please add appropriate after-procedure instructions to your DFU.

    b. You listed "Dura rupture" among the possible complications. However, the terminology, "Dura rupture" is unclear and not commonly used. Please revise the text to "Unintended durotomy" to improve the readability of your labeling.

    c. You do not include the lack of new bone formation as a potential adverse event (AE) in the use of your device. The clinical literature review that you submitted does not clearly demonstrate that there is new bridging bone formation across the calcium phosphate tiles. Therefore, please list in the DFU the lack of new bone formation as a possible complication for your device.

    d. You stated, "The dura may be sutured to the device" in Step 4 of the Procedure section in your DFU. While this practice of "dural tack-up stitches" in order to prevent epidural hematoma/seroma formation is commonplace among neurosurgeons, we do not recommend including this language in your DFU as your device has not been explicitly tested for this use and as such, the safety of this has not been assessed or demonstrated. Please remove this statement from your DFU. Alternatively, please provide clinical evidence to support the safety and effectiveness of this instruction.

4. You provided Magnetic Resonance (MR) Conditional labeling for your device. Several elements are inconsistent with the labeling recommendations in the Guidance for Industry and Food and Drug Administration Staff titled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" (issued December 11, 2014) and available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm107708.pdf. We believe that consistent labeling for MR Conditional information helps physicians, technologists, and others quickly identify the scanning conditions under which the device can be safely scanned. Please revise your MR Conditional information in the DFU to address the following and provided a red-lined and final clean copy of your revised DFU for our review:

    a. Please change the second bullet to "Maximum spatial field gradient of 3000 Gauss/cm (30 T/m)."

    b. Depending on any updates to your radiofrequency (RF) heating evaluation, please replace the third bullet that begins, "Maximum MR system reported,…" with "Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)."

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5. Your device is specifically created for a patient's unique anatomical requirements and can therefore be configured for a wide range of clinical needs. You provided RF-induced heating results showing less than 2 °C of temperature increase (b)(4) (b)(4) Confidential and Proprietary Information (b)(4) However, you did not test any other device configurations with clinically realistic sizes and shapes. Your proposed MR Conditional labeling does not limit the scans to device configurations according to your testing. Therefore, please limit your MR Conditional labeling to only those device configurations which were actually tested as the RF-induced heating of device configurations outside of the test samples are unknown. Alternatively, please provide RF-induced heating results for all clinically relevant device configurations (or justify the worst-case device configuration) and all scan conditions so that all patients with your device can be scanned safely using Magnetic Resonance Imaging (MRI).

6. Your MR Conditional labeling includes compatibility with 3 Tesla (T) MRI scanners. To improve image quality, 3 T MRI usually uses multi-channel transmit coils, i.e., RF shimming. However, your RF-induced heating test results only apply to quadrature transmit coils. Therefore, please change your MR Conditional labeling to allow scanning only for quadrature transmit coils by including an additional bullet point with: "*Quadrature transmit coils only*." Alternatively, please provide RF-induced heating test results for multi-channel transmit coils for all possible amplitude and phase configurations of the individual coil channels to allow patients implanted with your device to have more imaging capabilities.

7. Your MR Conditional labeling specifically excludes head transmit/receive coils, and you did not provide RF-induced heating test results for these coils. It is unknown whether you excluded head transmit/receive coils because of excess heating or because testing was not performed. Because patients with the OSSDSIGN AB Cranial PSI device have head injuries and are therefore in need of head scans, please modify your MR Conditional labeling to address compatibility with head transmit/receive coils, and address the following:

   a. Please provide RF-induced heating results for head transmit/receive coils, for all clinically relevant device configurations and all scan conditions. For 3 T head transmit/receive coils, please include all possible amplitude and phase configurations of the individual coil channels in the testing.

   b. Please be advised that a whole body average of 2 W/kg will result in nearly 6 W/kg in the head. Since the heating effect will depend on the local SAR, the region around the device could heat to unsafe levels. It should be noted that in the Normal level operating mode, the head SAR is controlled to 3.2 W/kg by MRI system software, which may be acceptable for your device. Therefore, please evaluate whether your RF heating safety statement should be modified to read as follows: *"Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg and head average SAR of < 3.2 W/kg (Normal Operating Mode)."*

Cleaning, Disinfection, Sterilization, Shelf-Life and Pyrogenicity

8. (b)(4) Confidential and Proprietary Information

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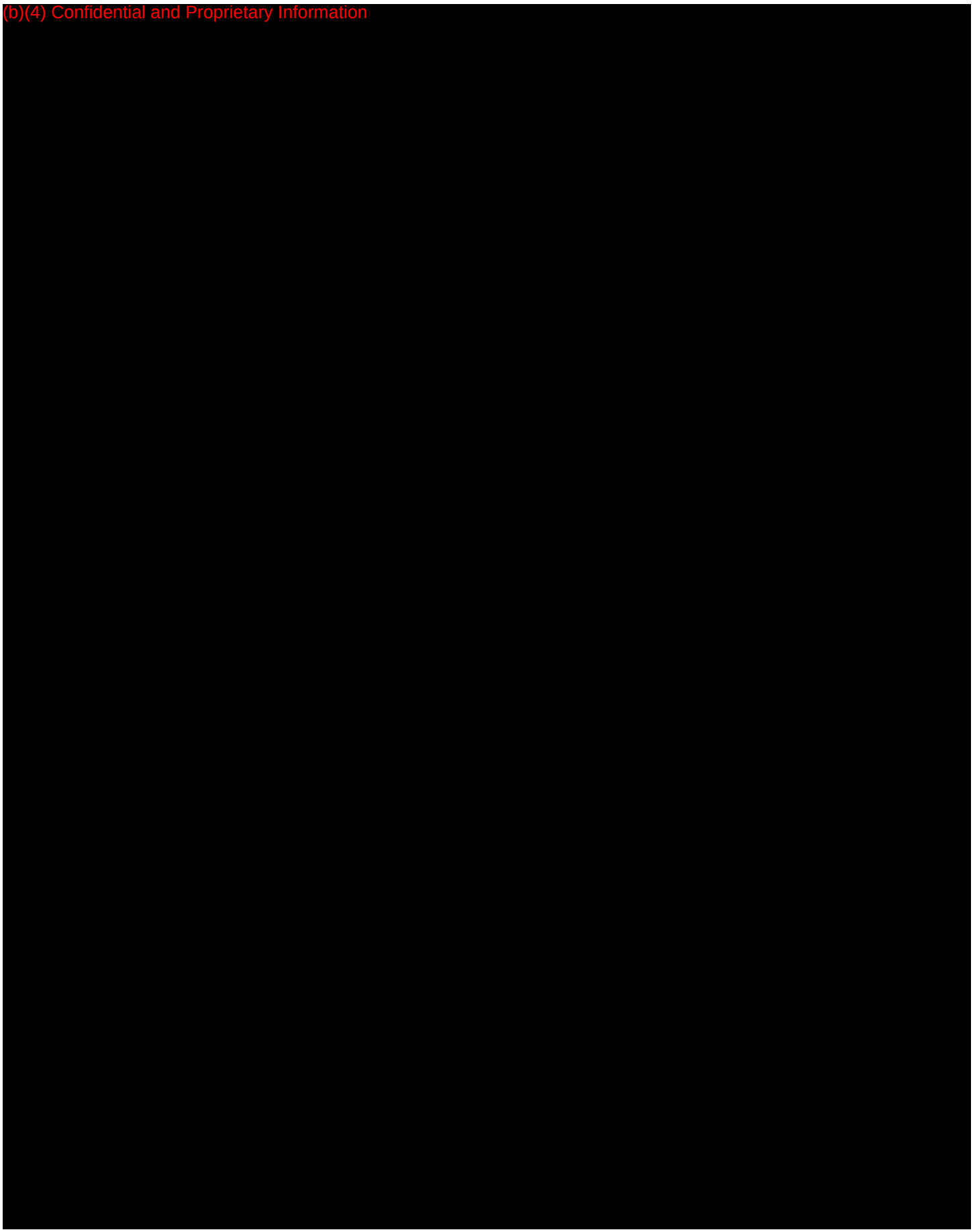
(b)(4) Confidential and Proprietary Information



Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

(b)(4) Confidential and Proprietary Information

[redacted]

9. You did not specify the shelf-life for your device. We believe the expiration for your device is important as your device contains materials that may degrade over time in addition to sterility concerns regarding the package integrity since your device is provided sterile. Please state your proposed shelf-life for the subject device and summarize the supporting evidence for this shelf-life in order to demonstrate substantial equivalence (e.g., package integrity, material stability, performance testing, etc.).

10. You reported that the level of endotoxin is monitored to ensure acceptable level and stability in production facilities in (b) (4) [redacted], *Validation of Production Facilities, Environment.* However, you do not specify the endotoxin specification required for Cranial PSI devices. The endotoxin release specification for cerebral spinal fluid (CSF) contacting devices with a neurological indication is < 2.15 EU/device, as discussed in FDA's Guidance for Industry, "Pyrogen and Endotoxin Testing: Questions and Answers" issued June 2012 and available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM310098.pdf. Therefore, please report the required endotoxin for the cranial PSI devices. In addition, please report the required endotoxin for the Cranial PSI devices. In addition, please provide the routine batch release procedures followed to ensure each lot of your device conforms to the required < 2.15 EU/device endotoxin lot release specification.

Biocompatibility

11. You provided biocompatibility data from tests conducted on a representative piece of your Cranial PSI device. Your device generally met the acceptance criteria for the various tests you conducted; however, the following concerns should be addressed before this data can be determined to be adequate:

    a. You stated that the Cranial PSI device can be re-sterilized one time (by vacuum assisted sterilizer). However, it is unclear if all biocompatibility testing was conducted on devices after a single sterilization or two sterilization cycles. Please clarify. We recommend that all biocompatibility testing be conducted on the "worst case" final sterilized device, and

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based on your re-sterilization instructions, a device having undergone 2 sterilization cycles would be considered the worst-case representative. The additional cleaning and sterilization may affect the device composition, with the potential to affect biocompatibility of the device. If testing was done after a single sterilization cycle, please provide justification as to why the biocompatibility testing you have conducted would still be valid for the device after 2 sterilization cycles (the worst case scenario). In addition, please address if the device may be compromised or if there are visible changes to the device after re-sterilization.

b. You extracted the test article using (b) (4) for all of your biocompatibility assays. ANSI/AAMI/ISO 10993-12:2012 *Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials* recommends that a surface area of the test article to volume of extraction vehicle ratio of 120 cm^2/20 ml (for device thickness of < 0.5 mm) or 60 cm^2/20 ml (for device thickness of ≥ 0.5 mm) be used for extraction. Per ANSI/AAMI/ISO 10993-12:2012, a mass of the test article to volume of extraction vehicle ratio of (b) (4) could only be used for extraction if the surface area cannot be determined due to the configuration of sample. Please provide justification for your use of a mass of the test article to volume of extraction vehicle ratio (b) (4) instead of a surface area to volume of the extraction vehicle ratio for preparing test article extracts. The use of weight instead of the surface area may result in a false negative finding (e.g., the negative finding may occur as a result of insufficient sample being present in the test system). In order to justify the use of (b) (4) for extraction, please demonstrate that the use of weight to determine extraction ratio results in the use of an equivalent or greater amount of test article as compared to use of the surface area.

c. (b)(4) Confidential and Proprietary Information

12. Your device is a permanent implanted device with tissue/bone and indirect blood contact through reabsorption of CSF into the venous system. Although your device utilizes commonly used materials, the biocompatibility of a device depends not only on the materials used but also on the processing of the materials, manufacturing method (including the cleaning and sterilization process), and manufacturing residuals that may be imparted on the final device (i.e., contaminants, such as additives, coolants, detergents, or any other processing aid that could adversely change or affect final composition or safety of the device). You have not conducted all of the testing recommended for your device according to ANSI/AAMI/ISO 10993-1:2009 (R2013) *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process* and the FDA's Blue Book Memorandum G95-1. Due to contact with CSF, please conduct indirect hemolysis and material-mediated pyrogenicity testing using the final, sterilized worst case representative device, with justification for the selection of representative devices. Additionally, subchronic and chronic systemic toxicity should be addressed. Subchronic toxicity and chronic toxicity

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may also be addressed as part of an implantation study at a clinically relevant site by including multiple time points and evaluation of appropriate endpoints or by including appropriate risk assessments for toxicity after an exhaustive chemical characterization study using your worst case representative device.

13. You have previously received recommendations from the FDA regarding the Cranial PSI device in two related Pre-Submissions (Q150051 and Q150051/S001) that have not been addressed in your current submission. Please provide the following or justify omitting this data:

    a. A test report describing qualitative and quantitative chemical residuals analysis (i.e., exhaustive extraction) on the final, sterilized Cranial PSI device that represents "the worst case" from a material residual perspective, and includes the following:

        i. Your rationale for the device size and extraction conditions selected.

        ii. Evaluation of the particle composition and size distribution that is extractable from the additive manufactured finished device.

        iii. A toxicological risk analysis on the chemicals and particles identified and quantified in the residuals extraction study.

    b. According to FDA's Blue Book memorandum G95-1, an implantation test is recommended for your device, which is a permanent implant with tissue/bone contact. ISO 10993-6 (*Biological Evaluation of Medical Devices – Tests for Local Effects After Implantation*) recommends that the implantation study should be conducted at a clinically relevant implant site to assess the local tissue response. Also, the standard recommends that for degradable/resorbable materials, the local tissue response shall be evaluated at various time points including the time point when there is no or minimal degradation, the time point when degradation is taking place and the time point when a steady state has been reached. Thus, unless justified otherwise, please provide implantation study data (using a clinically relevant site) on your device with a justification for the choice of the device size for the implantation study and the time points selected for evaluation.

    c. (b)(4) Confidential and Proprietary Information [redacted]

Performance Testing

14. You propose to label your device for a maximum defect size of 300 cm^2. However, your predicate device is not cleared for this maximum defect size. Additionally, you have not provided animal testing data or clinical data to provide evidence of the safe use of your device in 300 cm^2 defects. Therefore, please provide animal test data, clinical data, or any additional justification as scientific evidence to support the safe use of your device in this maximum defect size.

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(b)(4) Confidential and Proprietary Information

[redacted]

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

K161090
OSSDSIGN AB
Device Trade Name: Cranial PSI
Contact Name: Mr. David Weissburg

DEFICIENCY LIST

Administrative Information

1. You provided brief phrases and values regarding "Testing vs. predicates" in your 510(k) Summary. However, your brief phrases and omission of biocompatibility are not sufficient for the 510(k) Summary and do not provide a high level summary of the tests and leveraged data that were used to demonstrate the substantial equivalence of your device. Therefore, please revise your 510(k) Summary to include a discussion of the bench tests, biocompatibility tests, animal study(ies), and published literature described in your submission for a determination of substantial equivalence (e.g., purpose, test conditions, acceptance criteria similar to predicate device testing, etc.). In addition, please include the specific conclusions drawn from your performance testing that demonstrate the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices. Please provide a red-lined and final clean copy (e.g., no section numbers, stand-alone document with its own set of page numbering) of your revised 510(k) Summary for our review. For guidance, please refer to the sample table below for your presentation of the performance testing in the 510(k) Summary:

Test	Test Method Summary	Results
Name of Test	Description of test apparatus, conditions, duration, etc. In addition, this section can discuss the purpose of each type of bench testing.	Discussion of results such as all samples passed the acceptance criteria and the relevancy of the test result in determining the substantial equivalence of the proposed device.

2. You referenced several consensus standards for validation of the moist heat sterilization process, for endotoxin testing and for leveraging package verification/shelf-life testing. However, you do not provide a separate "Standards Data Report for 510(k)s" (FDA Form 3654) for each referenced consensus standard. A completed FDA Form 3654 should be submitted for each standard which you use to establish the substantial equivalence of your device. Therefore, please submit a completed FDA Form 3654 for each consensus standard used in sterilization validation, endotoxin testing and in package verification/shelf-life testing, in which you identify and justify any deviations to a related FDA recognized consensus standard. FDA's database of currently recognized consensus standards is located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Labeling

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3. Your proposed Directions for Use (DFU) include some information that is unclear and that could lead to unsafe use of your device. Please provide red-lined and clean copies of your DFU that addresses the following concerns:

    a. You listed "Patients who are potentially non-compliant with after-procedure instructions" among the Contraindications. However, you do not provide after-procedure instructions in your labeling as these instructions are particularly important for the safety of the patients that are implanted with large ceramic cranial implants. Please add appropriate after-procedure instructions to your DFU.

    b. You listed "Dura rupture" among the possible complications. However, the terminology, "Dura rupture" is unclear and not commonly used. Please revise the text to "Unintended durotomy" to improve the readability of your labeling.

    c. You do not include the lack of new bone formation as a potential adverse event (AE) in the use of your device. The clinical literature review that you submitted does not clearly demonstrate that there is new bridging bone formation across the calcium phosphate tiles. Therefore, please list in the DFU the lack of new bone formation as a possible complication for your device.

    d. You stated, "The dura may be sutured to the device" in Step 4 of the Procedure section in your DFU. While this practice of "dural tack-up stitches" in order to prevent epidural hematoma/seroma formation is commonplace among neurosurgeons, we do not recommend including this language in your DFU as your device has not been explicitly tested for this use and as such, the safety of this has not been assessed or demonstrated. Please remove this statement from your DFU. Alternatively, please provide clinical evidence to support the safety and effectiveness of this instruction.

4. You provided Magnetic Resonance (MR) Conditional labeling for your device. Several elements are inconsistent with the labeling recommendations in the Guidance for Industry and Food and Drug Administration Staff titled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" (issued December 11, 2014) and available at http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm107708.pdf. We believe that consistent labeling for MR Conditional information helps physicians, technologists, and others quickly identify the scanning conditions under which the device can be safely scanned. Please revise your MR Conditional information in the DFU to address the following and provided a red-lined and final clean copy of your revised DFU for our review:

    a. Please change the second bullet to "Maximum spatial field gradient of 3000 Gauss/cm (30 T/m)."

    b. Depending on any updates to your radiofrequency (RF) heating evaluation, please replace the third bullet that begins, "Maximum MR system reported,…" with "Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)."

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5. Your device is specifically created for a patient's unique anatomical requirements and can therefore be configured for a wide range of clinical needs. You provided RF-induced heating results showing less than 2 °C of temperature increas (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information (b) (4) However, you did not test any other device configurations with clinically realistic sizes and shapes. Your proposed MR Conditional labeling does not limit the scans to device configurations according to your testing. Therefore, please limit your MR Conditional labeling to only those device configurations which were actually tested as the RF-induced heating of device configurations outside of the test samples are unknown. Alternatively, please provide RF-induced heating results for all clinically relevant device configurations (or justify the worst-case device configuration) and all scan conditions so that all patients with your device can be scanned safely using Magnetic Resonance Imaging (MRI).

6. Your MR Conditional labeling includes compatibility with 3 Tesla (T) MRI scanners. To improve image quality, 3 T MRI usually uses multi-channel transmit coils, i.e., RF shimming. However, your RF-induced heating test results only apply to quadrature transmit coils. Therefore, please change your MR Conditional labeling to allow scanning only for quadrature transmit coils by including an additional bullet point with: "*Quadrature transmit coils only*." Alternatively, please provide RF-induced heating test results for multi-channel transmit coils for all possible amplitude and phase configurations of the individual coil channels to allow patients implanted with your device to have more imaging capabilities.

7. Your MR Conditional labeling specifically excludes head transmit/receive coils, and you did not provide RF-induced heating test results for these coils. It is unknown whether you excluded head transmit/receive coils because of excess heating or because testing was not performed. Because patients with the OSSDSIGN AB Cranial PSI device have head injuries and are therefore in need of head scans, please modify your MR Conditional labeling to address compatibility with head transmit/receive coils, and address the following:

   a. Please provide RF-induced heating results for head transmit/receive coils, for all clinically relevant device configurations and all scan conditions. For 3 T head transmit/receive coils, please include all possible amplitude and phase configurations of the individual coil channels in the testing.

   b. Please be advised that a whole body average of 2 W/kg will result in nearly 6 W/kg in the head. Since the heating effect will depend on the local SAR, the region around the device could heat to unsafe levels. It should be noted that in the Normal level operating mode, the head SAR is controlled to 3.2 W/kg by MRI system software, which may be acceptable for your device. Therefore, please evaluate whether your RF heating safety statement should be modified to read as follows: *"Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg and head average SAR of < 3.2 W/kg (Normal Operating Mode)."*

Cleaning, Disinfection, Sterilization, Shelf-Life and Pyrogenicity

8. (b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

[redacted]

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

(b)(4) Confidential and Proprietary Information

[redacted]

9. You did not specify the shelf-life for your device. We believe the expiration for your device is important as your device contains materials that may degrade over time in addition to sterility concerns regarding the package integrity since your device is provided sterile. Please state your proposed shelf-life for the subject device and summarize the supporting evidence for this shelf-life in order to demonstrate substantial equivalence (e.g., package integrity, material stability, performance testing, etc.).

10. You reported that the level of endotoxin is monitored to ensure acceptable level and stability in production facilities in (b) (4) [redacted], *Validation of Production Facilities, Environment.* However, you do not specify the endotoxin specification required for Cranial PSI devices. The endotoxin release specification for cerebral spinal fluid (CSF) contacting devices with a neurological indication is < 2.15 EU/device, as discussed in FDA's Guidance for Industry, "Pyrogen and Endotoxin Testing: Questions and Answers" issued June 2012 and available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM310098.pdf. Therefore, please report the required endotoxin for the cranial PSI devices. In addition, please report the required endotoxin for the Cranial PSI devices. In addition, please provide the routine batch release procedures followed to ensure each lot of your device conforms to the required < 2.15 EU/device endotoxin lot release specification.

Biocompatibility

11. You provided biocompatibility data from tests conducted on a representative piece of your Cranial PSI device. Your device generally met the acceptance criteria for the various tests you conducted; however, the following concerns should be addressed before this data can be determined to be adequate:

    a. You stated that the Cranial PSI device can be re-sterilized one time (by vacuum assisted sterilizer). However, it is unclear if all biocompatibility testing was conducted on devices after a single sterilization or two sterilization cycles. Please clarify. We recommend that all biocompatibility testing be conducted on the "worst case" final sterilized device, and

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based on your re-sterilization instructions, a device having undergone 2 sterilization cycles would be considered the worst-case representative. The additional cleaning and sterilization may affect the device composition, with the potential to affect biocompatibility of the device. If testing was done after a single sterilization cycle, please provide justification as to why the biocompatibility testing you have conducted would still be valid for the device after 2 sterilization cycles (the worst case scenario). In addition, please address if the device may be compromised or if there are visible changes to the device after re-sterilization.

b. You extracted the test article using (b) (4) for all of your biocompatibility assays. ANSI/AAMI/ISO 10993-12:2012 *Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials* recommends that a surface area of the test article to volume of extraction vehicle ratio of 120 cm^2/20 ml (for device thickness of < 0.5 mm) or 60 cm^2/20 ml (for device thickness of ≥ 0.5 mm) be used for extraction. Per ANSI/AAMI/ISO 10993-12:2012, a mass of the test article to volume of extraction vehicle ratio of (b) (4) could only be used for extraction if the surface area cannot be determined due to the configuration of sample. Please provide justification for your use of a mass of the test article to volume of extraction vehicle ratio (b) (4) instead of a surface area to volume of the extraction vehicle ratio extracts. The use of weight instead of the surface area may result in a false negative finding (e.g., the negative finding may occur as a result of insufficient sample being present in the test system). In order to justify the use of (b) (4) for extraction, please demonstrate that the use of weight to determine extraction ratio results in the use of an equivalent or greater amount of test article as compared to use of the surface area.

(b)(4) Confidential and Proprietary Information

[redacted]

12. Your device is a permanent implanted device with tissue/bone and indirect blood contact through reabsorption of CSF into the venous system. Although your device utilizes commonly used materials, the biocompatibility of a device depends not only on the materials used but also on the processing of the materials, manufacturing method (including the cleaning and sterilization process), and manufacturing residuals that may be imparted on the final device (i.e., contaminants, such as additives, coolants, detergents, or any other processing aid that could adversely change or affect final composition or safety of the device). You have not conducted all of the testing recommended for your device according to ANSI/AAMI/ISO 10993-1:2009 (R2013) *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process* and the FDA's Blue Book Memorandum G95-1. Due to contact with CSF, please conduct indirect hemolysis and material-mediated pyrogenicity testing using the final, sterilized worst case representative device, with justification for the selection of representative devices. Additionally, subchronic and chronic systemic toxicity should be addressed. Subchronic toxicity and chronic toxicity

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may also be addressed as part of an implantation study at a clinically relevant site by including multiple time points and evaluation of appropriate endpoints or by including appropriate risk assessments for toxicity after an exhaustive chemical characterization study using your worst case representative device.

13. You have previously received recommendations from the FDA regarding the Cranial PSI device in two related Pre-Submissions (Q150051 and Q150051/S001) that have not been addressed in your current submission. Please provide the following or justify omitting this data:

    a. A test report describing qualitative and quantitative chemical residuals analysis (i.e., exhaustive extraction) on the final, sterilized Cranial PSI device that represents "the worst case" from a material residual perspective, and includes the following:

        i. Your rationale for the device size and extraction conditions selected.

        ii. Evaluation of the particle composition and size distribution that is extractable from the additive manufactured finished device.

        iii. A toxicological risk analysis on the chemicals and particles identified and quantified in the residuals extraction study.

    b. According to FDA's Blue Book memorandum G95-1, an implantation test is recommended for your device, which is a permanent implant with tissue/bone contact. ISO 10993-6 (*Biological Evaluation of Medical Devices – Tests for Local Effects After Implantation*) recommends that the implantation study should be conducted at a clinically relevant implant site to assess the local tissue response. Also, the standard recommends that for degradable/resorbable materials, the local tissue response shall be evaluated at various time points including the time point when there is no or minimal degradation, the time point when degradation is taking place and the time point when a steady state has been reached. Thus, unless justified otherwise, please provide implantation study data (using a clinically relevant site) on your device with a justification for the choice of the device size for the implantation study and the time points selected for evaluation.

(b)(4) Confidential and Proprietary Information

[redacted]

Performance Testing

14. You propose to label your device for a maximum defect size of 300 cm^2. However, your predicate device is not cleared for this maximum defect size. Additionally, you have not provided animal testing data or clinical data to provide evidence of the safe use of your device in 300 cm^2 defects. Therefore, please provide animal test data, clinical data, or any additional justification as scientific evidence to support the safe use of your device in this maximum defect size.

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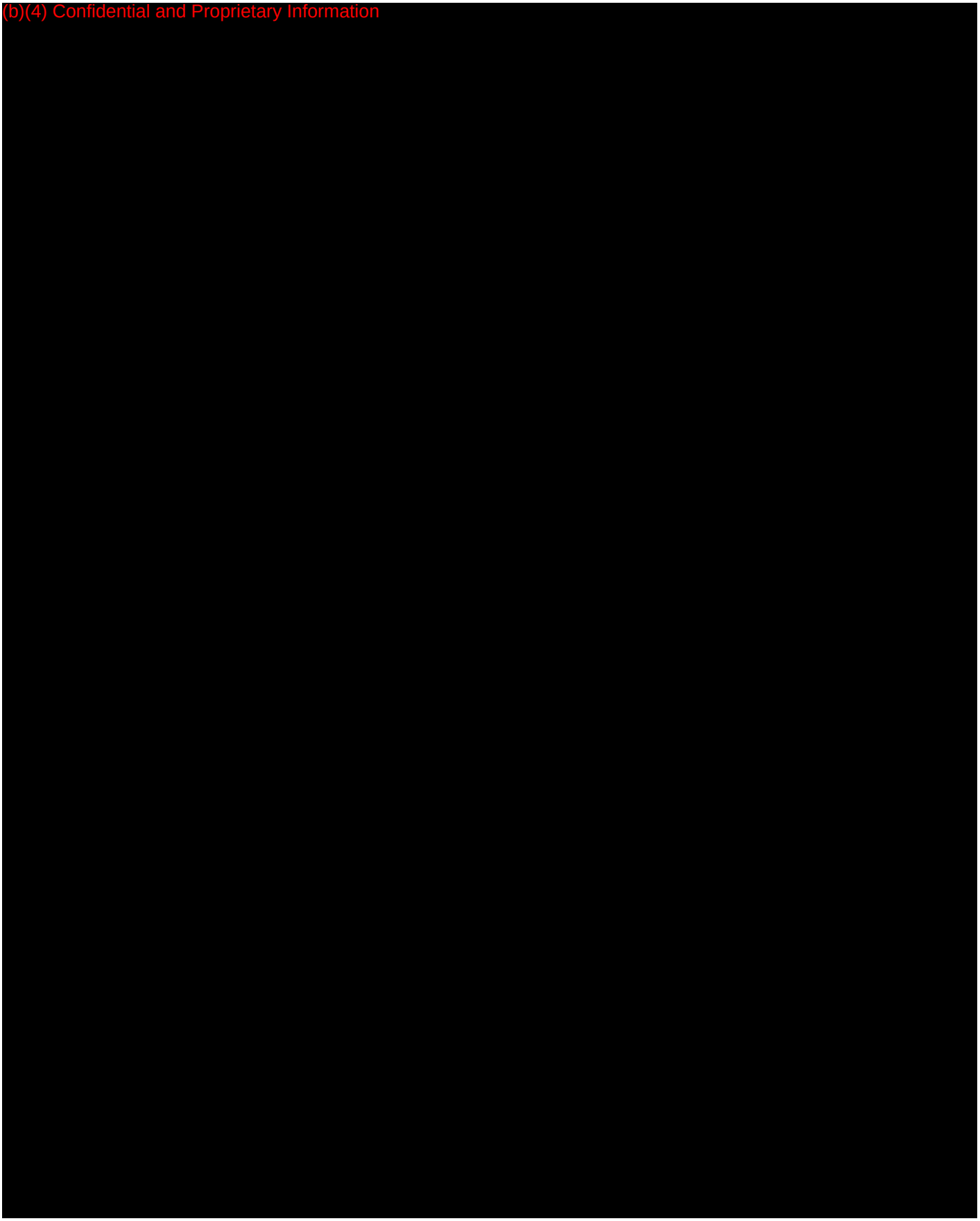
(b)(4) Confidential and Proprietary Information



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K161090

Device Name
OSSDSIGN Cranial PSI

Indications for Use *(Describe)*
OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K161090

Device Name
OSSDSIGN Cranial PSI

Indications for Use *(Describe)*
OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

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

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

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Food and Drug Administration
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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

January 19, 2017

OSSDSIGN AB
% David Weissburg
Principal
Weissburg Associates
808 Williamson Street, Suite 402
Madison, Wisconsin 53703

Re: K161090
Trade/Device Name: OSSDSIGN Cranial PSI
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PJN
Dated: December 13, 2016
Received: December 14, 2016

Dear Mr. Weissburg:

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

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

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

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

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

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Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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

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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

January 19, 2017

OSSDSIGN AB
% David Weissburg
Principal
Weissburg Associates
808 Williamson Street, Suite 402
Madison, Wisconsin 53703

Re: K161090
Trade/Device Name: OSSDSIGN Cranial PSI
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PJN
Dated: December 13, 2016
Received: December 14, 2016

Dear Mr. Weissburg:

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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Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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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

January 19, 2017

OSSDSIGN AB
% David Weissburg
Principal
Weissburg Associates
808 Williamson Street, Suite 402
Madison, Wisconsin 53703

Re: K161090
Trade/Device Name: OSSDSIGN Cranial PSI
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PJN
Dated: December 13, 2016
Received: December 14, 2016

Dear Mr. Weissburg:

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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Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K161090

Device Name
OSSDSIGN Cranial PSI

Indications for Use *(Describe)*
OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

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510(k) SUMMARY

K161090

1. 510(k) Owner Name and Address:
   OSSDSIGN AB
   Virdings Alle 2,
   SE 754 50, Uppsala
   Sweden
   Telephone: +46 (0) 18-55 39 93
   Email: ub@ossdsign.com
   Contact: Ulrik Birgersson

2. Contact Person:
   David Weissburg
   Weissburg Associates
   808 Williamson St., Suite 402
   Madison, Wisconsin, 53703 USA

3. Date prepared: January 18, 2017

4. Trade Name: OSSDSIGN Cranial PSI

5. Regulation Description: Preformed Non-alterable Cranioplasty Plate

6. Classification Name: Plate, Preformed Non-alterable Cranioplasty Plate (21 CFR 882.5330, Product code: PJN)

7. Class: 2

8. Substantially equivalent to: KLS Martin – Patient Contoured Mesh (K062570)

9. Device Description: OSSDSIGN Cranial PSI (Patient Specific Implant) is a device that replaces native bone in the cranial skeleton. Each Cranial PSI is a patient-specific device specifically created for a patient's unique anatomical requirements. Cranial PSI consists of a rigid titanium mesh that is largely covered by biocompatible ceramic tiles. The ceramic tiles are in a mosaic pattern that provides space between tiles to allow free circulation of fluids.

10. Indications for Use: OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.

11. Comparison of Technological Characteristics with the Predicate Device :

	OSSDSIGN Cranial PSI (K161090, subject device)	KLS Martin Patient Contoured Mesh (K062570, predicate)
Indications For Use	OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.	Patient Contoured Mesh (PCM) is intended to replace bony voids in mandibular, maxillofacial or craniofacial skeleton.
Materials	Ti grade 23, proprietary calcium phosphate ceramic	CP Titanium

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	OSSDSIGN Cranial PSI (K161090, subject device)	KLS Martin Patient Contoured Mesh (K062570, predicate)
Titanium thickness	0.4 – 1.6 mm	0.6 – 1.0 mm
Max size	200 cm^2	200 cm^2
Provided form	Titanium and Ceramic Ceramic mixed and cured in manufacturer's facility	Titanium only
Sterility on delivery	Sterile	Non-sterile

12. Testing vs. predicate:

Test Method and Relevance Summary	Results	
	OSSDSIGN Cranial PSI	KLS Martin - PCI Titanium Mesh (K062570)
	Size: 197 cm^2	Size: 197 cm2
Dynamical Load Test: To verify that the Cranial PSI supports the forces exerted onto the implant from sleeping during the device lifetime. Requirement: no deformation Method: orbital shaker, 125 rpm, 60 hours. Relevance: test simulates changed head position every 20 minutes during 8 hours sleep for 50 years. Both the subject device and predicate passed the test.	No deformation	No deformation
Max Force [N] To establish the maximum force that can be applied to the device before failure. Requirement: >100 N Method: Universal testing machine at 1 mm/min Relevance: protection from falling objects and blunt trauma. Both the subject device and predicate passed the test. The subject device provided moderately better performance than the predicate.	461	383
Energy absorption [mJ] To establish the maximum energy the device can absorb before failure. Requirement: >1000 mJ Method: Universal testing machine at 1 mm/min Relevance: protection from falling objects and blunt trauma. Both the subject device and	2260	3760

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predicate passed the test.		
Resistance to Deformation [mm] To establish device resistance to deformation before device failure. Requirement: <6 mm Method: Universal testing machine at 1 mm/min to 100 N applied force Relevance: Both the subject device and predicate passed the test.	0.5 mm	1.1 mm

13. Biocompatibility:

Test	Test Method Summary	Results
Cytotoxicity	ISO 10993-5 Method:L-929 mouse fibroblast cells	Not cytotoxic No evidence of causing cell lysis or toxicity
Sensitization	ISO 10993-10 Method: guinea pig maximization test	Non-sensitizer All test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.
Sensitivity, Irritation	ISO 10993-6 Method: polar and non-polar test article extracts intracutaneously injected into five separate sites on the right side of the back of three rabbits. Observations for erythema and edema were conducted at 24, 48, and 72 hours.	Non-irritant Difference between the test and the control mean scores <1.0, confirming the device is a non-irritant
Systemic (acute) toxicity	ISO 10993-11 Method: 20 mice observed at 4, 24, 48 and 72 hours.	Non-toxic No mortality or evidence of systemic toxicity
Genotoxicity	ISO 10993-3 Method: mouse lymphoma forward gene mutation assay.	Not mutagenic <2-fold increase in mean mutant frequency of the L5178Y/TK cell line.
Mutagenicity	ISO-10993-3 Method: bacterial reverse mutation study	Non-mutagenic <2-fold increase in mutagenic frequency.
Implantation	ISO 10993-6 Test for local effects after implantation, 2- and 6-week subcutaneous implantations in rabbits.	Non-irritant Non-irritant compared to control.

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

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Analytical Extractable Chemical Analysis	ISO 10993-12 Analysis by GC-MS, ICP-MS, LC-MS and HPLC-ELSD	Non-hazardous in all results, including extractions in polar, non-polar and mid-polar solvents. No hazardous materials detected.
Indirect Hemolysis	ISO 10993-4 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	The hemolytic index for the test article extract was 3.8% and the test article extract was slightly hemolytic. All samples passed the acceptance criteria.
Material Mediated Pyrogenicity	ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity, Pyrogen Test	The total rise of temperatures during the 3 hour observation period was within acceptable limits. The test article was judged as nonpyrogenic. All samples passed the acceptance criteria

14. Conclusions:

Nonclinical tests demonstrate that Cranial PSI is as safe, as effective, and performs as well as or better than the legally marketed predicate device identified in this summary.

- Cranial PSI mechanical performance in a battery of life-style emulating test scenarios shows substantial equivalence in mechanical effectiveness compared to the predicate device
- Cranial PSI demonstrated biocompatibility per current consensus standards

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Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

Hello Dr. Kittlesen,

FDA's document center today received OssDsign's Submission Issue Q-Sub for the Cranial PSI device (K161090), which is presently on 180 day FDA hold.

I appreciate that you will receive this Q-Sub through FDA's document system; attached is an additional copy.

Following your first read of our Q-Sub, please let me know if anything seems unclear or begs additional information.

Thank you for your consideration,

David Weissburg
(b) (6)
[redacted]

(b)(4) Confidential and Proprietary Information - Draft Instructions For Use

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Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

This document contains the contents of the Instructions For Use of *OSSDSIGN Cranial PSI* for the USA market.

Document Control Number printed on the IFU: 2017-2053 Rev03

The Instructions For Use (IFU) is compromised of the tables below. Symbols and their meanings are both included in the IFU. The Master Text may be formatted to appropriately fit a specific document.

OSSDSIGN® Cranial PSI Instructions For Use
PATIENT-SPECIFIC DEVICE
Indications for Use: OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete and for use with an intact dura, with or without duraplasty.
Warnings • The Instructions For Use must be read and understood prior to clinical use. • *OSSDSIGN Cranial PSI* is MR Conditional; see important restrictions under MR Safety Information, below. • Care must be taken to assure that screws do not protrude into the dura. Screws must be shorter than the thickness of the bone into which they are being inserted.
MRI Safety Information   **MR Conditional** Non-clinical testing and electromagnetic simulations demonstrated that the *OSSDSIGN Cranial PSI* is MR Conditional. A patient with this device can be scanned safely in an MR system after implantation under the following conditions: • Static magnetic field of 1.5-Tesla or 3-Tesla • Maximum spatial field gradient of 3000 Gauss/cm (30 T/m) • Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg

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(Normal Operating Mode) and head average SAR of <3.2 W/kg (Normal Operating Mode)

- Body coil only, do not use head transmit/receive coil
- Quadrature transmit coils only

Under the scan conditions defined above, the *OSSDSIGN Cranial PSI* is expected to produce a maximum temperature rise of 2˚ C after 15-minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the Cranial PSI extends approximately 7 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Introduction

OSSDSIGN Cranial PSI (Patient Specific Implant, PSI) is an implanted device that replaces native bone in the cranial skeleton. Each *OSSDSIGN Cranial PSI* is a patient-specific device specifically created for a patient's unique anatomical requirements. *OSSDSIGN Cranial PSI* consists of a titanium mesh that is largely covered by calcium phosphate ceramic tiles. The titanium mesh provides mechanical stability. The ceramic tiles provide favorable cosmetic outcome by more naturally following the curvature of the skull. *OSSDSIGN Cranial PSI* is made from biocompatible material that allows for host tissue integration. The ceramic tiles are designed in a mosaic pattern with space between tiles that allows for circulation of fluids.

Contraindications

OSSDSIGN Cranial PSI is not intended for use with:

1. Patients with incomplete cranial growth
2. Infected areas
3. Procedures or applications other than those described in the *OSSDSIGN Cranial PSI* Instructions For Use
4. Patients with foreign body sensitivity or metal allergies
5. Patients who are potentially non-compliant with after-procedure instructions common to all implants, such as observing standard wound healing instructions and to use care with the anatomical location such as avoiding blows to the head
6. Screws of any length that may contact the dura

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

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Precautions

1. Before implanting *OSSDSIGN Cranial PSI* the surgeon should position the device according to the Directions for Use described in the *OSSDSIGN Cranial PSI Instructions For Use*. Incorrectly placed devices will affect the functional and aesthetical outcome of the procedure. Before implantation: read and understand all Contraindications, Warnings, Precautions, Directions and the Intended Use. Before beginning the procedure, assure all necessary components for the procedure are present.
2. *OSSDSIGN Cranial PSI* is delivered pre-formed to fit the defect of the specific patient for whom it was designed. The procedure can proceed even if an individual tile has been damaged or has detached from the device during operation. This will not reduce the stability of the device.
3. This device may only be used by properly trained and experienced medical personnel working in a sterile operating environment.
4. The surgeon is responsible for proper selection of appropriate patients and procedures, the adequacy of medical personnel training and experience, and all decisions to remove other implants.
5. Radiotherapy after implantation may require alternate dosing and planning to account for the presence of the device.
6. *OSSDSIGN Cranial PSI* is carefully designed to fit a specific patient's defect. If the surgeon desires to modify the fit, bone must be removed from the patient defect using standard surgical procedures. Do not remove material from the OSSDSIGN Cranial PSI. No cutting or reshaping of the device is permitted. For best results, implant within six months from date of manufacture.
7. Excessive screw tightening may cause loose titanium or bone fragments. Any such fragments must be removed.
8. Excessive screw tightening may cause screws to strip out of the bone intended for attachment. If a screw hole strips out, emergency or self-tapping screws may be used, following the Instructions For Use of the screw manufacturer. Do not use screws of a length that may contact the dura.
9. To reduce the risk of pulling out a screw, wiggle the screwdriver to loosen the screwdriver-screw connection prior to disengaging the screwdriver from the screw.
10. Screws must be removed prior to explantation. The device is integrated into neighboring bone and soft tissue over time, which may affect the surgical procedure if explantation is required.
11. Fastening arms may be gently adjusted to improve the fit.
12. Dispose of, and do not implant any product that has been explanted, damaged or mishandled prior to the operation.
13. USA federal law restricts the use of this device to sale by or on the order of a physician.

Sterility

OSSDSIGN Cranial PSI is delivered sterile and is confirmed to remain sterile for one year from date of manufacture. Sterilization method used by the manufacturer is steam sterilization (20 minutes, 121˚C). The manufacturer cannot guarantee device sterility if the inner package seal is broken or if the package is improperly opened or the product mishandled. The device may not be re-sterilized.

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

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Storage information
Store between 4-34˚C (40-93˚F)

Possible complications

1. Unintended durotomy from using screws which contact the dura
2. Titanium allergy
3. Tile or tile chips loosening during operation. Remove tile or tile chip and proceed with implantation.
4. Device does not fit due to changes in the patient's defect size due to either bone growth or bone resorption occurring since the CT scan was performed

Date of last revision
This Instructions For Use was last revised January 2017

Directions for Use

Step 1.
Confirm *OSSDSIGN Cranial PSI* product labeling, patient ID, expiration date, quantity on hand and intact sterility barrier before starting surgery.

Step 2
The defect is surgically exposed according to the procedure elected by the surgeon.

Step 3.
Care is taken by the surgeon to properly orient the *OSSDSIGN Cranial PSI* relative to the defect and the device is fitted into position with fastening arms overlapping healthy skull bone (Figure 1.).

- OSSDSIGN Cranial PSI is carefully designed to fit a specific patient's defect. If the surgeon desires to modify the fit, bone must be removed from the patient defect using standard surgical procedures. Do not remove material from the OSSDSIGN Cranial PSI. No cutting or reshaping of the device is permitted.
- Fastening arms may be gently adjusted to improve the fit.

Step 4.
OSSDSIGN Cranial PSI is attached to surrounding bone using tapered (counter-sunk) titanium screws suitable for application in the skull, inserted into the fastening arms (Figure 2.).

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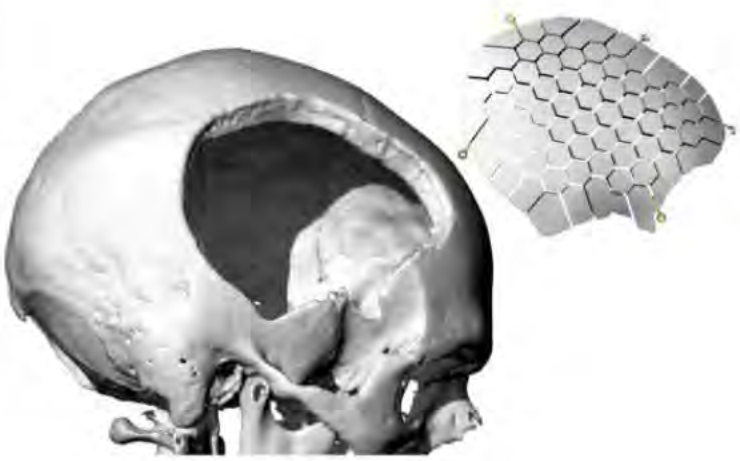
Step 5. Close wound according to the procedure elected by the surgeon.

Figure 1.	

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

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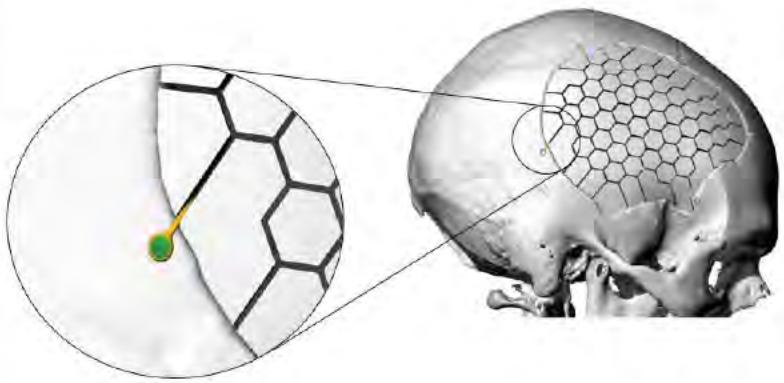
Figure 2.	

Symbol	Symbols are used in *OSSDSIGN Cranial PSI* labels and printed materials. Their meanings are defined below:
	OSSDSIGN AB Virdings Alle 2 SE 754 50, Uppsala, Sweden
℞only	Federal (USA) law restricts this device to sale or on the order of physician
REF	Article number
SN	Serial number (label only)

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(Example)	Unique Device Identifier (label only)
	Date of manufacture
	Shelf life/ Last day of use (label only)
	Temperature storage conditions
	Sterilized using steam or dry heat
	Do not re-use
	Do not re-sterilize
	Warnings
	Do not use if package is damaged
	Read the Instructions For Use
	Fragile, handle with care

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

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MR Conditional	Important safety restrictions for patient exposure to MR fields. See IFU or www.ossdsign.com

Revision history

Revision	Date	Cause of revision
01	7 April 2016	New Document
02	8 Dec 2016	Updated in response to FDA feedback
03	15 Jan 2017	Updated in response to FDA feedback

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

(b)(4) Confidential and Proprietary Information - Reports

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Contains Nonbinding Recommendations

Print Form

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.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K161090 Date Received by DCC: Apr 18, 2016

Lead Reviewer: Gregg Kittlesen, Ph.D.

Branch: NNDB Division: DNPMD Center/Office: CDRH/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 the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X		
Comments:			
2. Is the submission with the appropriate Center? 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 submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	X		
Comments:			
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: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **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?** 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 the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			X
Comments:			

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4) Is this device type eligible for a 510(k) submission? 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."	X		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) 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 http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."			X
Comments:			

- 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.
- 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 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

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Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		
Comments:			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- 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.

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format.* *(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	X				
6) Submission is a Class III 510(k) device.			X		
7) Submission contains clinical data	X				
a) Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry- Financial Disclosures by Clinical Investigators.*			X		
b) Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*			X		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	X				
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	X				
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				
c) A list and description of each device for which clearance is requested.	X				
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.			X		
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., 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				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
a) Indications for Use	X				
b) Technology, including features, materials, and principles of operation	X				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
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				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X				
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.			X		
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X		
E. Sterilization					
If an *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.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
X Provided sterile, intended to be single-use					
Requires processing during its use-life					
Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
Sterility status not needed for this device (e.g., software-only device)					
Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.	X				
c) Identification of device, and/or accessories, and/or components that are reusable.			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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	X				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X				
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.			X		
d) Sterility Assurance Level (SAL) is stated.	X				
e) Submission includes description of packaging.	X				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).			X		
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:					
a) Cleaning method is provided in labeling for each device, and/or accessory, and/or component.	X				
b) Disinfection method is provided in labeling for each device, and/or accessory, and/or component.			X		
c) Sterilization method is provided in labeling for each device and/or accessory, and/or component.	X				
d) Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."			X		
i) If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions.			X		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.			X		
F. Shelf Life					
24) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	X				
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	X				
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
× Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
Patient contact information not needed for this device (e.g., software-only device)					
Patient contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	×				
28) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	×				
29) 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).	×				
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					
× Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
Software/firmware information not needed for this device (e.g., surgical suture, condom)					
Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
I. Electrical Safety and EMC					
Electrical Safety Submission states that the device: (one of the below must be checked)					
Does require electrical safety evaluation					

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

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
X Does not require electrical safety evaluation					
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
Electrical safety information not needed for this device (e.g., surgical suture, condom)					
Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
EMC Submission states that the device: (one of the below must be checked)					
Does require EMC evaluation					
X Does not require EMC evaluation					
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
EMC information not needed for this device (e.g., surgical suture, condom)					
EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.					
34) 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.	X				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	X				
35) The device has a device-specific guidance document, special controls document, and/ or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.			X		
36) If literature is referenced in the submission, submission includes:					
a) Legible reprints or a summary of each article.	X				
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	X				
37) For each completed animal study, the submission provides the following:			X		
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)					
is an in vitro diagnostic device.					

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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. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Decision: ◉ Accept ○ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Gregg Kittlesen -S 2016.04.27 15:15:45 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

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CONSULTING REVIEW

To: Gregg Kittlesen, Ph.D.
ODE/DNPMD/NNDB

From: Daniel Krainak, Ph.D.
Office of *In Vitro* Diagnostics and Radiological Health (OIR)
Division of Radiological Health (DRH)
Magnetic Resonance and Electronic Products Branch (MREP)

Digital Signature Concurrence Table	
Reviewer Sign-Off	Daniel Krainak -S 2016.05.26 16:37:10 -04'00'

Subject: K161090
OSSDSIGN Cranial PSI
OSSDSIGN AB

(b)(4) Confidential and Proprietary Information and (b)(5)

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

K161090
OSSDSIGN Cranial PSI Device

Date: 27 MAY 2016

To: Gregg Kittlesen
CDRH/ODE/DNPMD/NNDB

From: Dr. Wolfgang Kainz
CDRH/OSEL/DP
301 661 7595

Recommendation: see deficiencies below

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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Biocompatibility Review

Memorandum

Date:	May 31, 2016
To:	Gregg Kittlesen, Ph.D., Lead Reviewer DNPMD/NNDB
From:	Dhanya Williams, M.S. Biologist/Scientific Reviewer, DNPMD/NNDB
Reviewer Electronic Signature:	Dhanya K. Williams -S 2016.06.01 09:40:22 -04'00'
Subject:	K161090
Applicant:	Ulrik Birgersson Clinical Engineering Director OssDsign AB Virdings Alle 2 Uppsala SE 754 50 Sweden +46 (0) 18-55 39 93 ub@ossdsign.com
Device (Trade name):	OSSDSIGN Cranial PSI (Patient Specific Implant)
Device (Regulation name):	Plate, Cranioplasty, Preformed, Non-Alterable (21CFR882.5330)
Contact:	David Weissburg Weissburg Associates – Principal 808 Williamson St., Suite 402 Madison, WI 53703 david.weissburg@gmail.com 608-770-0223
Recommendation:	**Additional Information Needed (AINN)**

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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Date: June 8, 2016

From: Myra Smith, Microbiologist DNPMD/NNDB

Myra K. Smith -S
2016.06.08 12:27:26 -04'00'

To: Gregg Kittlesen, Ph.D., DNPMD/NNDB, Lead Reviewer
cc: The Record

Subject: K161090: Microbiology Consult
Device: Cranial PSI
Applicant: OssDsign AB

(b)(4) Confidential and Proprietary Information and (b)(5)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Division of Neurological and Physical Medicine Devices
Neurodiagnostic and Neurosurgical Devices Branch

Food and Drug Administration
Office of Device Evaluation
Center for Devices and Radiological Health

Date: 6/17/2016
To: FILE; Gregg Kittlesen, Ph.D.

CC: Xiaolin Zheng, Ph.D.
From: Sheng-fu Larry Lo, M.D.
Subject: OSSDSIGN Cranial PSI
Product Code: GXN
Sponsor: OSSDSIGN AB
Virdings Alle 2
Uppsala SE 754 50
Sweden
Contact: David Weissburg
Principal, Weissburg Associates
david.weissburg@gmail.com
608-7708-0223

K161090 OSSDSIGN Cranial PSI

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Food and Drug Administration
CDRH/ODE/DNPMD/NNDB
WO66 RM2615
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6473 x6473

Premarket Notification 510(k) Review

Date: June 17, 2016

Reviewer: Gregg Kittlesen

Subject: Traditional 510(k)# K161090

Applicant: OSSDSIGN AB	**Device Trade Name:** Cranial PSI
Contact Name: David Weissburg	**Contact Title:** Principal
Correspondent Firm: Weissburg Associates	**Phone:** (608) 770-0223 **Email:** david.weissburg@gmail.com
Received Date: April 18, 2016	**Due Date:** July 17, 2016
Pro Code(s): GXN **Class:** II **Reg #:** 882.5330	**Reg Name:** Preformed Nonalterable Cranioplasty Plate

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K062570	GXN	Patient Contoured Mesh (PCM)	KLS-Martin L.P.

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug
Administration

Memorandum

K161090-S001
OSSDSIGN Cranial PSI Device

Date: 21 DEC 2016

To: Gregg Kittlesen
CDRH/ODE/DNPMD/NNDB

From: Dr. Wolfgang Kainz
CDRH/OSEL/DP
301 661 7595

Recommendation: approval

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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

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Biocompatibility Review

Memorandum

Date:	January 19, 2017
To:	Gregg Kittlesen, Ph.D., Lead Reviewer DNPMD/NDNB
From:	Dhanya Williams, M.S. Biologist/Scientific Reviewer, DNPMD/NIDB
Reviewer Electronic Signature:	Dhanya K. Williams -S Digitally signed by Dhanya K. Williams -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300222984, cn=Dhanya K. Williams -S Date: 2017.01.19 15:17:35 -05'00'
Subject:	K161090/S001
Applicant:	Ulrik Birgersson Clinical Engineering Director OssDsign AB Virdings Alle 2 Uppsala SE 754 50 Sweden +46 (0) 18-55 39 93 ub@ossdsign.com
Device (Trade name):	OSSDSIGN Cranial PSI (Patient Specific Implant)
Device (Regulation name):	Plate, Cranioplasty, Preformed, Non-Alterable (21CFR882.5330)
Contact:	David Weissburg Weissburg Associates – Principal 808 Williamson St., Suite 402 Madison, WI 53703 david.weissburg@gmail.com 608-770-0223
Recommendation:	**Substantially Equivalent (SESE)**

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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Department of Health & Human Services **Food and Drug Administration**

MEMORANDUM

Hyung-yul Lee -A
2017.01.06 12:37:31
-05'00'

Date: January 6, 2016

To: Gregg Kittlesen, PhD
Team Leader
DNPMD/NSDB

From: Hyung Lee, PhD
Sterility Reviewer
DNPMD/NSDB

Cc: The Record

Device Name: Cranial Patient Specific Implant (PSI)

Sponsor: OSSDSIGN

(b)(4) Confidential and Proprietary Information and (b)(5)

[redacted]

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Division of Neurological and Physical Medicine Devices
Neurodiagnostic and Neurosurgical Devices Branch

Food and Drug Administration
Office of Device Evaluation
Center for Devices and Radiological Health

Date: 1/13/2017
To: FILE; Gregg Kittlesen

CC: Jay Gupta
From: Sheng-fu Larry Lo
Subject: OSSDSIGN Cranial PSI
Product Code: GXN
Sponsor: OSSDSIGN AB
Virdings Alle 2
Uppsala SE 754 50
Sweden
Contact: David Weissburg
Principal, Weissburg Associates
david.weissburg@gmail.com
608-7708-0223

K161090/S001 OSSDSIGN Cranial PSI

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
CDRH/ODE/DNPMD/NNDB
WO66 RM2615
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6473 x6473

Premarket Notification 510(k) Review

Date: January 19, 2017

Reviewer: Gregg Kittlesen

Subject: Traditional 510(k)# K161090/S001

Applicant: OSSDSIGN AB	**Device Trade Name:** Cranial PSI
Contact Name: David Weissburg	**Contact Title:** Principal
Correspondent Firm: Weissburg Associates	**Phone:** (608) 770-0223 **Email:** david.weissburg@gmail.com
Received Date: December 14, 2016	**Due Date:** January 13, 2017
Pro Code(s): PJN **Class:** II **Reg #:** 882.5330	**Reg Name:** Preformed Nonalterable Cranioplasty Plate

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K062570	GXN	Patient Contoured Mesh (PCM)	KLS-Martin L.P.

(b)(4) Confidential and Proprietary Information and (b)(5)

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K161090

FDA/CDRH/DCC
APR 18 2016
RECEIVED

OSSDSIGN
BETTER BONE REPAIR

Virdings Allé 2
SE-754 50 Uppsala
Sweden

Weissburg Associates
808 Williamson Street, #402
Madison, Wisconsin 53703
(b) (6) [redacted]

April 14, 2016

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

RE: 510(k) Cover Letter – OSSDSIGN Cranial PSI

The eCopy is an exact duplicate of the paper copy.

Dear Sir or Madam,

This Cover Letter conveys key information regarding our premarket submission for the OSSDSIGN Cranial PSI device.

OSSDSIGN AB is a Swedish medical device company located in Uppsala, Sweden. Anders Lundqvist is the CEO and has >25 years of USA medical device experience. David Weissburg is Principal of Weissburg Associates, a regulatory consultancy. He has >30 years of USA medical device experience and has successfully filed over 25 premarket submissions with the FDA.

Throughout your review, please call or email David Weissburg with any questions you may have.

- (b) (6) [redacted] am located in Madison, Wisconsin and you may call me 24/7.
- (b) (6) [redacted]

OSSDSIGN Cranial PSI is a titanium cranioplasty plate with bioactive calcium phosphate ceramic tiles. Materials are nearly identical to the OSSDSIGN Cranioplug001 (K140309) burr hole cover.

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

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Due to the similarities of these devices, certain reports and data that were developed for Cranioplug001 are included in this submission and pertain equally to Cranial PSI. Biocompatibility Testing is one such area.

In June 2012, OSSDSIGN received "Specialanpassad Product" clearance for Cranial PSI from Lakemedelsverket (the Swedish medical products agency). This clearance allows Cranial PSI to be sold throughout Europe. Cranial PSI is registered as custom-made device in accordance with European Medical Device Directive Annex VIII. A custom-made device is not eligible for CE marking, so the above clearance method is the proper regulatory approach. OSSDSIGN received ISO 13845 quality system certification in January, 2014. European clinical use[redacted]

(b)(4) Confidential and Proprietary Information

The Cranial PSI has undergone several name changes and one significant design change. Prior names that have been used in reports and FDA correspondence include: Mosaic, Mosaik, and Craniomosaic.

Prior Submissions: OSSDSIGN requested and received guidance from FDA on three occasions. Key guidance concepts and the location in this submission of OSSDSIGN's application of guidance are summarized below. Gregg Kittlesen, PhD was the FDA reviewer for our prior and pending premarket submissions: K140309 (Cranioplug001, cleared) and K160452 (Cranioplug002, pending).

(b)(4) Confidential and Proprietary Information

This guidance request pertained primarily to Mosaik, an earlier design of Cranial PSI, which

(b)(4) Confidential and Proprietary Information

(b) (4) Remaining relevant guidance topics include:

1. Compression strength and fracture toughness testing – (b) (4) Cranial PSI Bench Performance Testing
2. Characterization of the chemical and physical properties – see Cranial PSI Materials List (b) (4) Trace Element Analysis Report
3. Shelf-life stability testing – (b) (4) Shelf Life

Q150051 (FDA correspondent Gregg Kittlesen, PhD):
This guidance request pertained to Craniomosaic, an earlier name for the current design Cranial PSI. Much of this guidance document referred to planned *in vivo* testing to demonstrate

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

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(b)(4) Confidential and Proprietary Information

[redacted]

Per (21 CFR 807.95), OSSDSIGN requests that this submission and the subsequent written communication with FDA be held in confidence by FDA and not distributed to any third party. We request that this restriction be applied to the maximum extent possible but with exceptions necessary to enable FDA to meet its statutory requirements.

Respectfully submitted,

(b) (6)

[redacted]

David Weissburg

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

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted]

Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

OSSDSIGN AB
Virdings Alle 2 SE 75450 Uppsala Sweden

SE

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
David Weissburg

2.1 E-MAIL ADDRESS
(b) (6) [redacted]

2.2 TELEPHONE NUMBER (include Area code)
(b) (6) [redacted]

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center

[X] CDRH
[ ] CBER

3.2 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD165140

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

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

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

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

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

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[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) Confidential and Proprietary Information

28-Feb-2016

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

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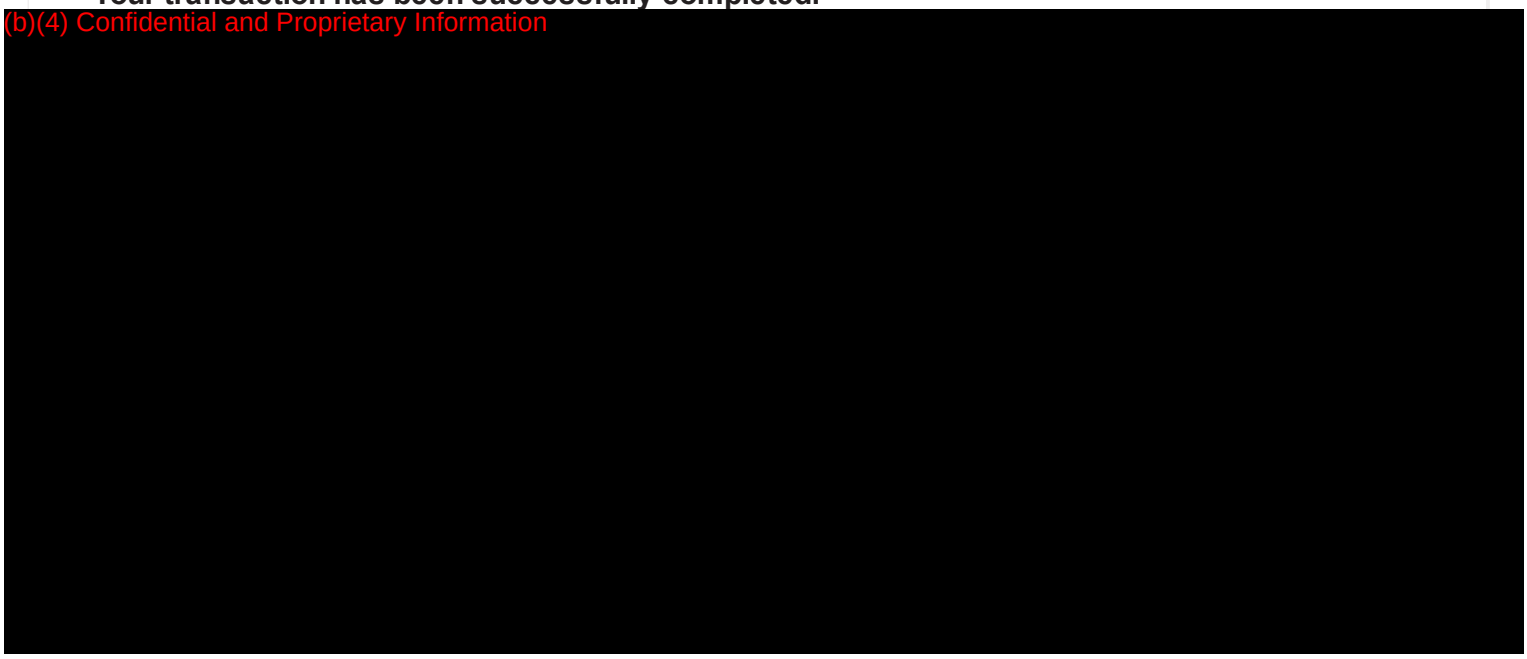
Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

(b)(4) Confidential and Proprietary Information



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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
13Apr2016	(b) (4)	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
OSSDSIGN AB			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	+46 (0) 18-55 39 93		
Street Address	**FAX Number *(including area code)***		
Virdings Alle 2	ub@ossdsign.com		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Uppsala		SE 754 50	Sweden
Contact Name			
Ulrik Birgersson			
Contact Title	**Contact E-mail Address**		
Clinical Engineering Director	ub@ossdsign.com		

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

Company / Institution Name			
Weissburg Associates			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(b) (6)		
Street Address	**FAX Number *(including area code)***		
808 Williamson St., Suite 402	(b) (6)		
City	**State / Province**	**ZIP Code**	**Country**
Madison	Wisconsin	53703	USA
Contact Name			
David Weissburg			
Contact Title	**Contact E-mail Address**		
Principal	(b) (6)		

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

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

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

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

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

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

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

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

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify):*

SECTION D2 — REASON FOR APPLICATION - IDE

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

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

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

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

- [ ] Other Reason *(specify):*

SECTION D3 — REASON FOR SUBMISSION - 510(k)

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

- [ ] Other Reason *(specify):*

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GXN	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K062570 (predicate, same titanium material and mechanical performance)	1	Patient Contoured Mesh (PCM), Plate, Cranioplasty, Preformed, Non-Alterable	1	KLS-MARTIN L.P
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Plate, Cranioplasty, Preformed, Non-Alterable (Patient-specific Implant made of Ti, PEEK or PMMA) (21CFR882.5330)

	Trade or Proprietary or Model Name for This Device		Model Number
1	Cranial PSI	1	patient-specific design
2		2	
3		3	
4		4	
5		5	

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

1 Q130597	2 K140309	3 Q150051	4 Q160519	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	C.F.R. Section *(if applicable)*	Device Class
GXN	21 CFR 882.5330	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Neurology

Indications *(from labeling)*

OSSDSIGN Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete.

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Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number *(if known)*

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: OSSDSIGN AB		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*: +46 (0) 18-55 39 93	
Street Address: Virdings Alle 2		FAX Number *(including area code)*: ub@ossdsign.com	
City: Uppsala	State / Province	ZIP Code: SE 754 50	Country: Sweden
Contact Name: Ulrik Birgersson	Contact Title: Clinical Engineering Director	Contact E-mail Address: ub@ossdsign.com	

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

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

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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	EN-ISO 13485	ISO	Quality Management	2012	01/01/2012
2	ISO 14971	ISO	Medical Devices – Application of risk management to medical risk	2012	01/01/2012
3	ISO 10993	ISO	Biological evaluation of medical devices.	1: 2009 14: 2009 17: 2009	01/01/2009
4	ASTM F1635-11	ASTM	Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer	2011	01/01/2011
5	ISO 14937	ISO	Sterilization of health care products	2009	01/01/2009
6	ISO 13060	ISO	Sterilization of health care products with steam sterilization	2004	01/01/2004
7	ISO 23317	ISO	Implants for surgery — In vitro evaluation for apatite-forming ability of implant materials	2014	06/15/2014

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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

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See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
OSSDSIGN AB

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
14Apr16

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Virdings Allé 2
SE-754 50 Uppsala
Sweden

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +46-18-55 39 93
(Fax) +48-18-490 32 64

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)
OSSDSIGN Cranial PSI - Plate, Cranioplasty, Preformed, Non-Alterable
(21 CFR 882.5330, Product code: GXN)

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*
NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (b) (6) [redacted]

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Ulrik Birgersson, PhD
(Title) Clinical Engineer

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Virdings Allé 2
SE-754 50 Uppsala
Sweden

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) +46 - 18-55 39 93
(Fax) +48-18-490 32 64

15. DATE OF CERTIFICATION
14Apr16

Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 443-6740 EF

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OSSDSIGN
BETTER BONE REPAIR

Virdings Allé 2
SE-754 50 Uppsala
Sweden

Weissburg Associates
808 Williamson Street, #402
Madison, Wisconsin 53703
(b) (6)

April 14, 2016

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

RE: 510(k) Cover Letter – OSSDSIGN Cranial PSI

The eCopy is an exact duplicate of the paper copy.

Dear Sir or Madam,

This Cover Letter conveys key information regarding our premarket submission for the OSSDSIGN Cranial PSI device.

OSSDSIGN AB is a Swedish medical device company located in Uppsala, Sweden. Anders Lundqvist is the CEO and has >25 years of USA medical device experience. David Weissburg is Principal of Weissburg Associates, a regulatory consultancy. He has >30 years of USA medical device experience and has successfully filed over 25 premarket submissions with the FDA.

Throughout your review, please call or email David Weissburg with any questions you may have.

- Cell is (b) (6). I am located in Madison, Wisconsin and you may call me 24/7.

(b) (6)

OSSDSIGN Cranial PSI is a titanium cranioplasty plate with bioactive calcium phosphate ceramic tiles. Materials are nearly identical to the OSSDSIGN Cranioplug001 (K140309) burr hole cover.

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Due to the similarities of these devices, certain reports and data that were developed for Cranioplug001 are included in this submission and pertain equally to Cranial PSI. Biocompatibility Testing is one such area.

In June 2012, OSSDSIGN received "Specialanpassad Product" clearance for Cranial PSI from Lakemedelsverket (the Swedish medical products agency). This clearance allows Cranial PSI to be sold throughout Europe. Cranial PSI is registered as custom-made device in accordance with European Medical Device Directive Annex VIII. A custom-made device is not eligible for CE marking, so the above clearance method is the proper regulatory approach. OSSDSIGN received ISO 13845 quality system certification in January, 2014 (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information

The Cranial PSI has undergone several name changes and one significant design change. Prior names that have been used in reports and FDA correspondence include: Mosaic, Mosaik, and Craniomosaic.

Prior Submissions: OSSDSIGN requested and received guidance from FDA on three occasions. Key guidance concepts and the location in this submission of OSSDSIGN's application of guidance are summarized below. Gregg Kittlesen, PhD was the FDA reviewer for our prior and pending premarket submissions: K140309 (Cranioplug001, cleared) and K160452 (Cranioplug002, pending).

(b)(4) Confidential and Proprietary Information

This guidance request pertained primarily to Mosaik, an earlier design of Cranial PSI, which OSSDSIGN no longer produces and which will not be introduced into the USA market. The Cranial PSI device which is the subject of this submission is additively manufactured by 3D printing the titanium mesh to each patient's specific requirements. Weld joints originally specified in Q130597 are no longer used. As such, several guidance topics from Q130597 are no longer relevant. Remaining relevant guidance topics include:

1. Compression strength and fracture toughness testing – see (b) (4) - Cranial PSI Bench Performance Testing
2. Characterization of the chemical and physical properties – see Cranial PSI Materials List (b) (4) and (b) (4) Appendix IV - Trace Element Analysis Report
3. Shelf-life stability testing – see (b) (4) - Shelf Life

Q150051 (FDA correspondent Gregg Kittlesen, PhD):
This guidance request pertained to Craniomosaic, an earlier name for the current design Cranial PSI. Much of this guidance document referred to planned *in vivo* testing (b) (4) (b)(4) Confidential and Proprietary Information (b) (4) Remaining relevant guidance topics include:

1. (b)(4) Confidential and Proprietary Information
2. Manufacturing residuals – see (b) (4) Cleaning Validation in (b) (4) (b) (4) or residuals analysis of the additively manufactured titanium mesh and (b) (4) ranial PSI Biocompatibility Summary, Appendix IV - Trace Element Analysis Report regarding the entire post-sterilized device.
3. Performance testing with shape-matched predicates covering a range of clinically typical sizes – see (b) (4) - Bench and Predicate Performance Data

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(b)(4) Confidential and Proprietary Information [redacted]

Per (21 CFR 807.95), OSSDSIGN requests that this submission and the subsequent written communication with FDA be held in confidence by FDA and not distributed to any third party. We request that this restriction be applied to the maximum extent possible but with exceptions necessary to enable FDA to meet its statutory requirements.

Respectfully submitted,

(b) (6) [redacted]

David Weissburg

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Indications for Use

April 14, 2016

510(k) Number: _____

Device Name: OSSDSIGN Cranial PSI

Indications for Use:

(b)(4) Confidential and Proprietary Information - Draft

[redacted]

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) SUMMARY

(b)(4) Confidential and Proprietary Information - Draft Summary

[redacted]

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(b)(4) Confidential and Proprietary Information - Draft Summary

[redacted]

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Premarket Notification Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as an employee and Clinical Engineer of OSSDSIGN AB, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(b) (6)

[redacted]

2016 - Apr - 14

(Date)

_____

*(Premarket Notification [510(k)] Number)

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

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

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

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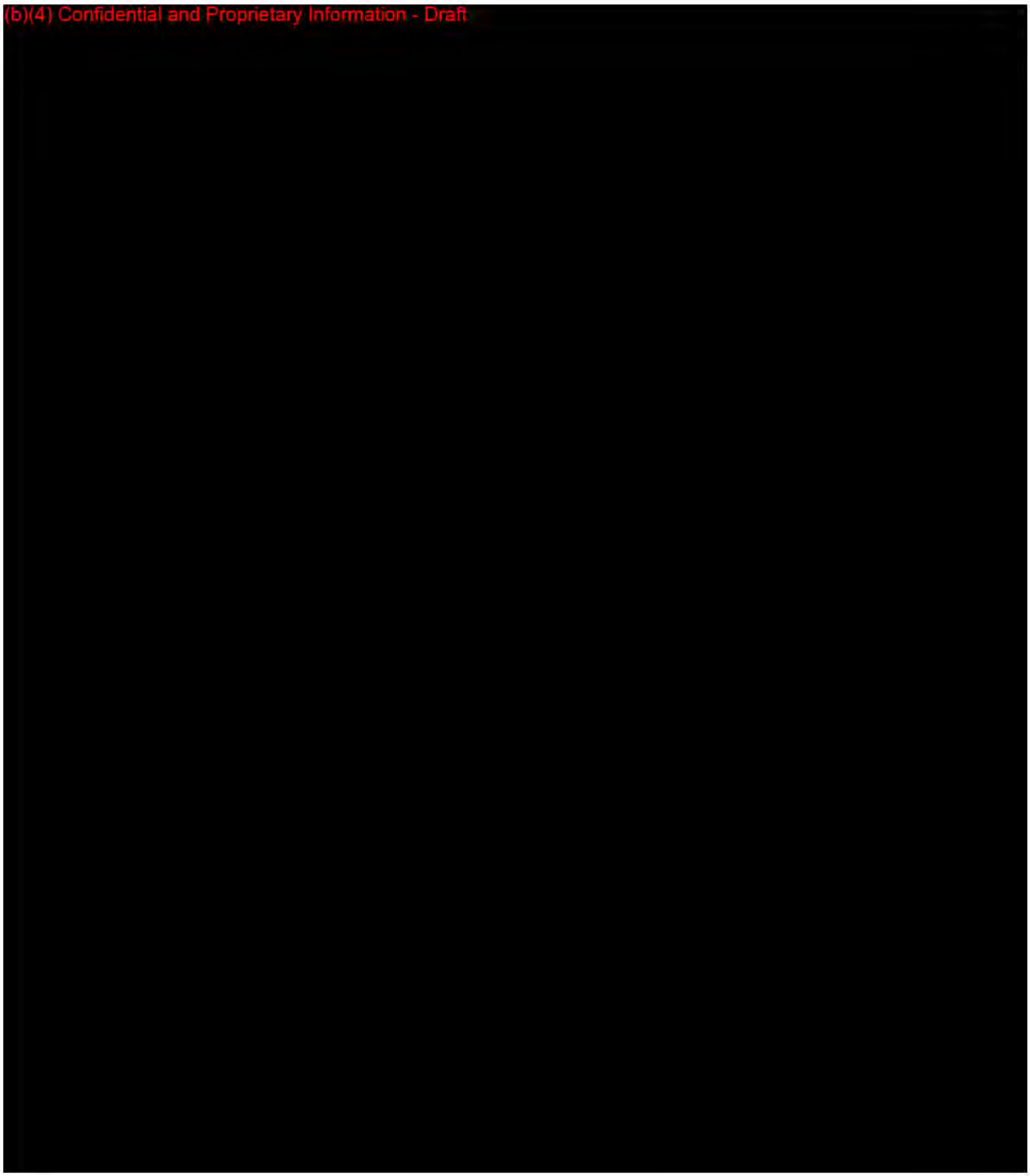

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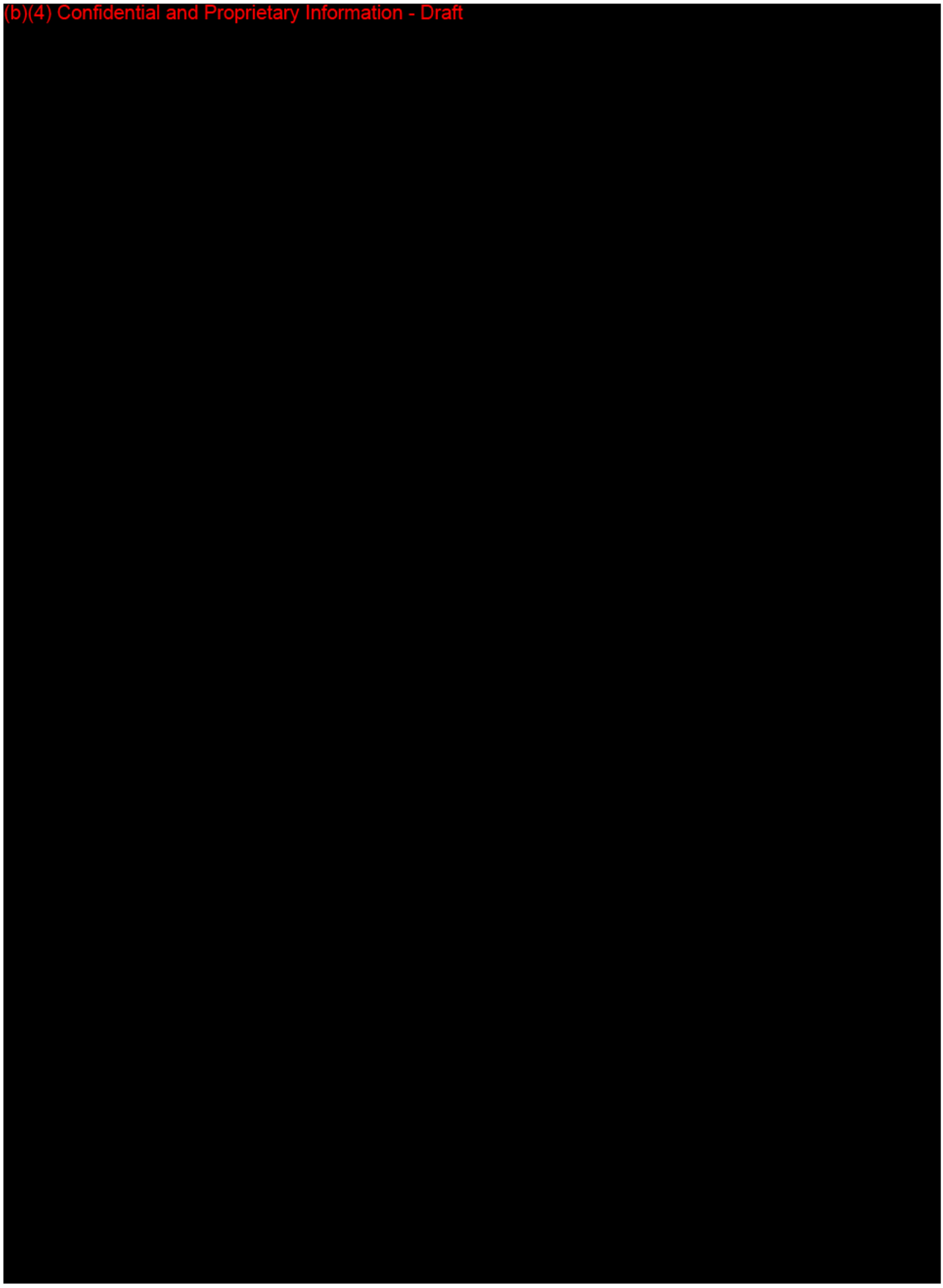
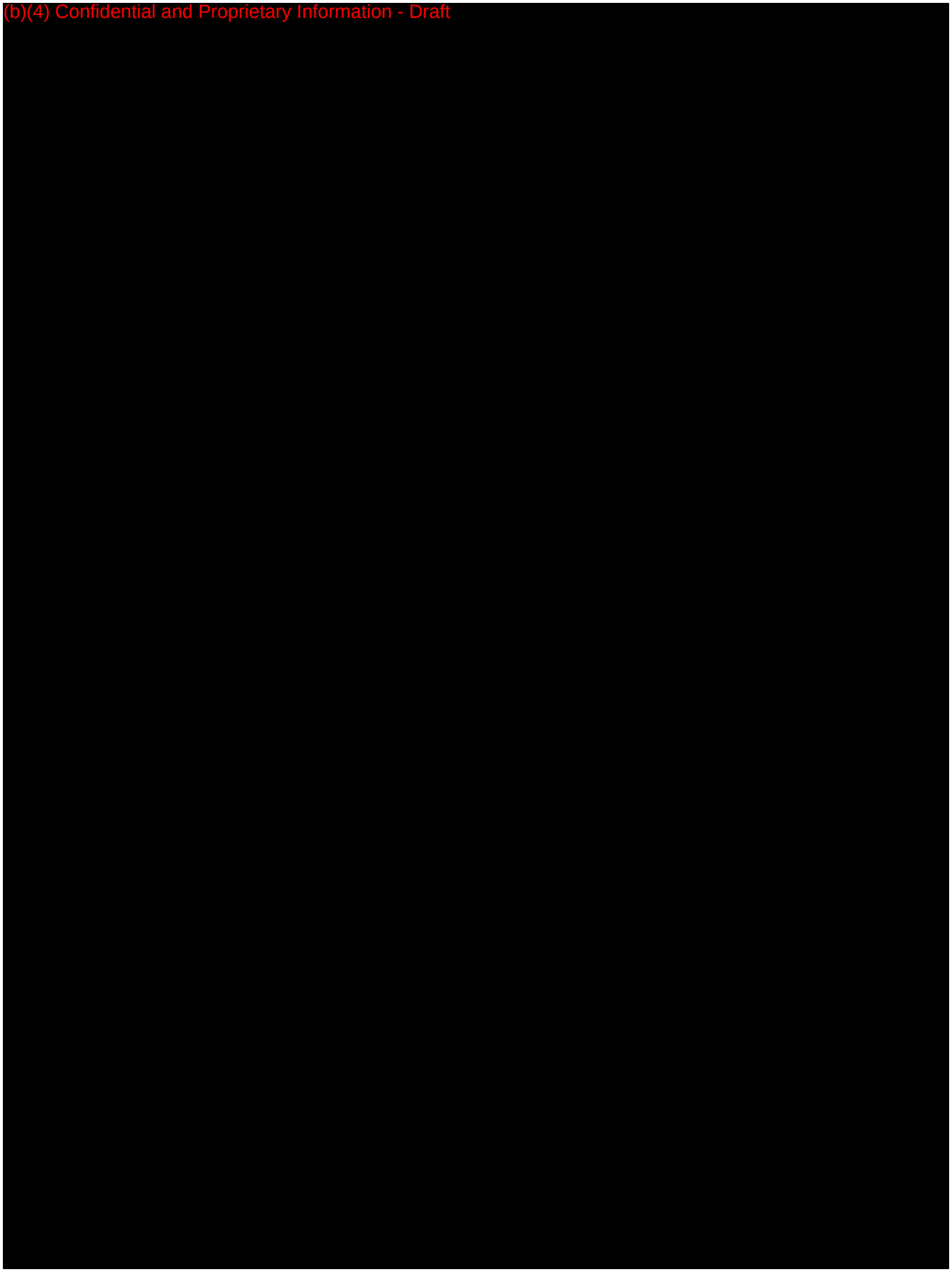


Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.



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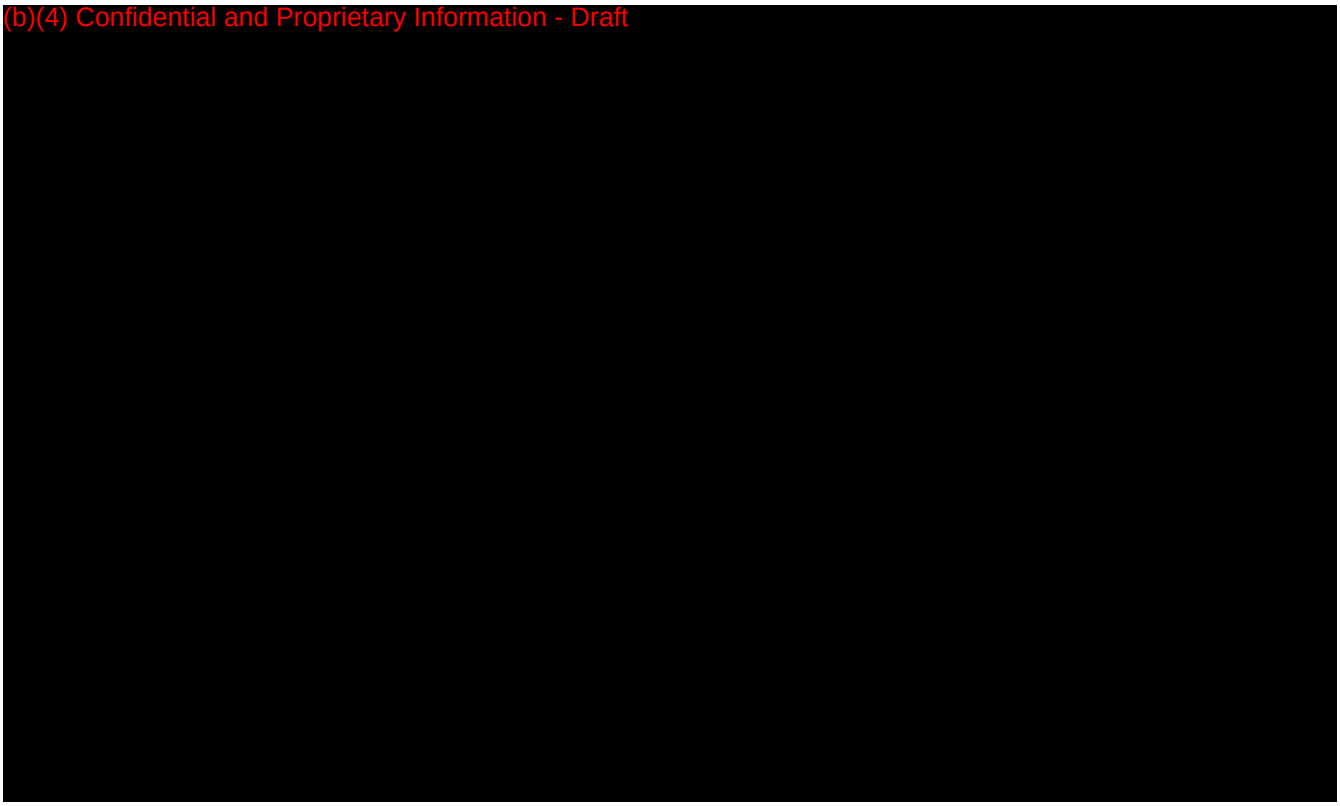
(b)(4) Confidential and Proprietary Information - Draft



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Patient Contoured Implants

every one is unique

Products
- Implants
  - Cranial
    - Cranio Sculpt
    - Titanium & PEEK Osteosynthesis
      - Cranial Loop
      - Patient Contoured Implants
      - Pre-contoured mesh
      - Specialty Burr-Hole Covers & Mesh
      - Low Profile Neuro System
      - Ultra Low Profile System (ULP)
    - SonicWeld Rx® Resorbable Osteosynthesis
    - Distraction Dev ces
    - Protective Helmets

Titanium & PEEK Cranial Osteosynthesis

Cranial Loop

Patient Contoured Implants

Pre-contoured mes

01 02 03 04 05 06

Appl cat on Fields

OMF Surgery
Neuro Surgery
ENT

Patient Contoured Implants

Remember

The ideal solution for reconstruction of cranial defects is one that is absolutely symmetr cal and functional for each indiv dual patient. With the readily available and cost effective CT scanning technology in hospitals, KLS Martin can manufacture an ideal implant with CT data.

Contact your local KLS Martin Sales Consultant

For each situat on the perfect implant

The solut on is perfect - and as unique as the patient, but it is something we can accomplish with absolute efficiency and precision.

After the CT Scan is obtained and sent to KLS Martin via email or upload, the process can begin immediately. The team includes your local sales consultant, CT Solution product manager and the engineers. A free solut on is generated for your approval before we manufacture the implant.

For each case the right material

Highly advanced materials are available for your implant - each w th its specific properties that make t part cularly suitable for specific fields of use. Our large range of sophisticated manufacturing facilities enables us to cope with any challenge.

Reconstruction no longer requires hand bending weaker, malleable flat meshes and requires a fraction of the time it once did. The precis on of the reconstruction is predictable and

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

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Trust us with your next Patient Contoured Implant, all we need is a CT scan to get started.

Order a Patient Contoured Implant

The information presented on this page is intended to demonstrate a KLS Martin® LP product. Please refer to package insert for the full list of indications, contraindications, warnings, precautions, and sterilization information. Always refer to the package insert before using any KLS Martin® L.P. product. Surgeons must always rely on their own clinical judgment when deciding which products and techniques to use with their patients.

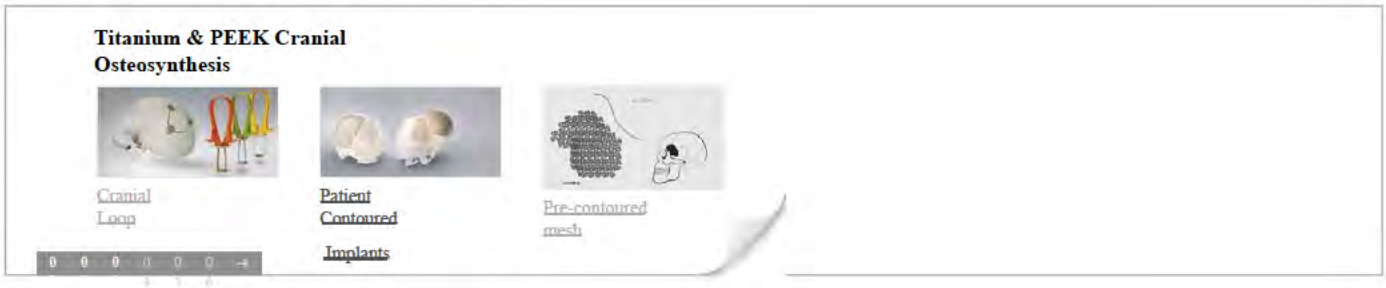
KLS Martin® LP, a member of the KLS Martin Group

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

Patient Contoured Implants

every one is unique

KLS martin GROUP



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Patient Contoured Implants Remember Add to Bookmark List

The ideal solution for reconstruction of cranial defects is one that is absolutely symmetrical and functional for each individual patient. With the readily available and cost effective CT scanning technology in hospitals, KLS Martin can manufacture an ideal implant with CT data.

For each situation the perfect implant

The solution is perfect - and as unique as the patient, but it is something we can accomplish with absolute efficiency and precision.

After the CT Scan is obtained and sent to KLS Martin via email or upload, the process can begin immediately. The team includes your local sales consultant, CT Solution product manager and the engineers. A free solution is generated for your approval before we manufacture the implant.

For each case the right material

	PEEK	Titanium mesh	Solid titanium
Subsequent implant correction	+	++	–
Mechanical strength	+++	++	+++
Biocompatibility	+++	+++	++
Thermal conductivity	+++	+	–
Price level	+	+++	++
Osseous integration potential	+	+++	++
Volume reconstruction	+++	+	+++
Artifact likelihood	+++	++	+

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Highly advanced materials are available for your implant - each with its specific properties that make it particularly suitable for specific fields of use. Our large range of sophisticated manufacturing facilities enables us to cope with any challenge.

Reconstruction no longer requires hand bending weaker, malleable flat meshes and requires a fraction of the time it once did. The precision of the reconstruction is predictable and satisfying to both doctor and patient.

Trust us with your next Patient Contoured Implant, all we need is a CT scan to get started.

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(b) (4) [redacted]

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FDA/CDRH/DCC
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(b) (6) [redacted]

December 13, 2016

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

RE: K161090/A001 Additional Information – OSSDSIGN Cranial PSI

(b) (6) [redacted]

The eCopy is an exact duplicate of the paper copy.

Reviewer: Gregg Kittlesen, PhD, Materials Engineer, CDRH/ODE/DNPMD/NNDB, WO66 - 2615

Dear Sir or Madam,

This Additional Information submission pertains to the OSSDSIGN Cranial PSI premarket submission K161090.

Prior Submissions: Since the submission of the original K161090, OssDsign AB received guidance from FDA on two occasions:

1. 17Jun16 Deficiency List from Gregg Kittlesen, PhD
2. Q161165 9Aug16 Guidance Teleconference and subsequent revised meeting minutes

Other FDA guidance was received prior to the initial submission of K161090, and is documented in that submission.

This Additional Information submission K161090/A001 responds to all issues raised by FDA in the 17Jun16 Deficiency List and 9Aug16 Guidance Teleconference.

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

2

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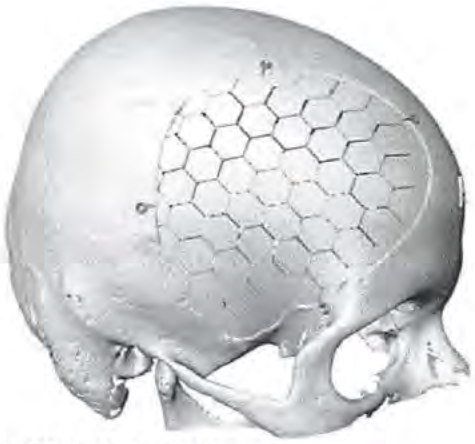
Throughout this document, the text that is in this Times Roman font has been copied from FDA's Deficiency List and Revised Meeting Minutes. Text in Calibri Font conveys OssDsign's response and additional information. This Additional Information submission is referred to in this report as AI#1.

Per (21 CFR 807.95), OssDsign AB requests that this submission and the subsequent written communication with FDA be held in confidence by FDA and not distributed to any third party. We request that this restriction be applied to the maximum extent possible but with exceptions necessary to enable FDA to meet its statutory requirements.

Respectfully submitted,

(b) (6)

David Weissburg



OSSDSIGN Cranial PSI

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(b) (6) [redacted]

December 13, 2016

Food and Drug Administration
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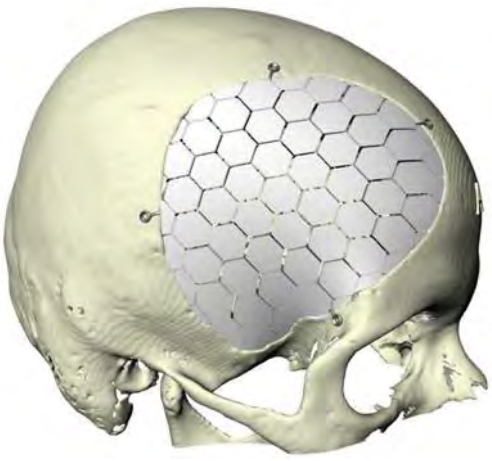
David Weissburg



OSSDSIGN Cranial PSI

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

Claims:

In the 9Aug16 Q161165 meeting revised meeting minutes, FDA advised:

"Additional Information: OssDsign will include with its submitted additional information the revised set of claims and their justification (b) (4)

(b)(4) Confidential and Proprietary Information

The table below summarizes initial and revised claims, and identifies the location of the associated justification for the remaining claims.

	Claims	K161090 OS	AI#1	Justification
1	Intended for the reconstruction of cranial defects	✓	✓	AI#1 response 1
2	Biocompatible	✓	✓	AI#1 responses 11, 12, 13
3	MR Conditional	✓	✓	AI#1 responses 4, 5, 6, 7

(b)(4) Confidential and Proprietary Information

6	Max device size	300 cm2	200 cm2	K161090 OS page 688

(b)(4) Confidential and Proprietary Information

8	Intended for use with an intact dura, with or without duraplasty		✓	AI#1 response 12

(b)(4) Confidential and Proprietary Information

Responses to FDA 17Jun16 Deficiency List

Administrative Information:

1. You provided brief phrases and values regarding "Testing vs. predicates" in your 510(k) Summary. However, your brief phrases and omission of biocompatibility are not sufficient for the 510(k) Summary and do not provide a high level summary of the tests and leveraged data that were used to demonstrate the substantial equivalence of your device. Therefore, please revise your 510(k) Summary to include a discussion of the bench tests, biocompatibility tests, animal study(ies), and published literature described in your submission for a determination of substantial equivalence (e.g., purpose, test conditions, acceptance criteria similar to predicate device testing, etc.). In addition, please include the specific conclusions drawn from your performance testing that demonstrate the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices. Please provide a red-lined and final clean copy (e.g., no section numbers, stand-alone document with its own set of page numbering) of your revised 510(k) Summary for our review. For guidance, please refer to the sample table below for your presentation of the performance testing in the 510(k) Summary:

Test	Test Method Summary	Results

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

Name of Test	Description of test apparatus, conditions, duration, etc. In addition, this section can discuss the purpose of each type of bench testing.	Discussion of results such as all samples passed the acceptance criteria and the relevancy of the test result in determining the substantial equivalence of the proposed device.

The requested changes have been made. Redline and blackline (clean) revisions of 510(k) Summary, v3 0 are included in this submission, see page 33.

2. You referenced several consensus standards for validation of the moist heat sterilization process, for endotoxin testing and for leveraging package verification/shelf-life testing. However, you do not provide a separate "Standards Data Report for 510(k)s" (FDA Form 3654) for each referenced consensus standard. A completed FDA Form 3654 should be submitted for each standard which you use to establish the substantial equivalence of your device. Therefore, please submit a completed FDA Form 3654 for each consensus standard used in sterilization validation, endotoxin testing and in package verification/shelf-life testing, in which you identify and justify any deviations to a related FDA recognized consensus standard. FDA's database of currently recognized consensus standards is located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

An updated summary document "Performance Standards and Regulations, OSSDSIGN Cranio Devices, 11Dec16" and all Forms 3654 for each referenced standard are included in this submission, see page 43.

Labeling

3. Your proposed Directions for Use (DFU) include some information that is unclear and that could lead to unsafe use of your device. Please provide red-lined and clean copies of your DFU that addresses the following concerns:

Redline and blackline (clean) copies of the revised IFU are conveyed in:

- (b) (4) IFU Master Text, OSSDSIGN Cranial PSI, USA v2 0, and
- (b) (4) IFU Master Text, OSSDSIGN Cranial PSI, USA v2 0 redline

These start on page 77 of this submission.

a. You listed "Patients who are potentially non-compliant with after-procedure instructions" among the Contraindications. However, you do not provide after-procedure instructions in your labeling as these instructions are particularly important for the safety of the patients that are implanted with large ceramic cranial implants. Please add appropriate after-procedure instructions to your DFU.

This contraindication is intended as a general warning common to all cranial implants. The IFU has been changed to add the following italicized text: Patients who are potentially non-compliant with after-procedure instructions *common to all implants,*

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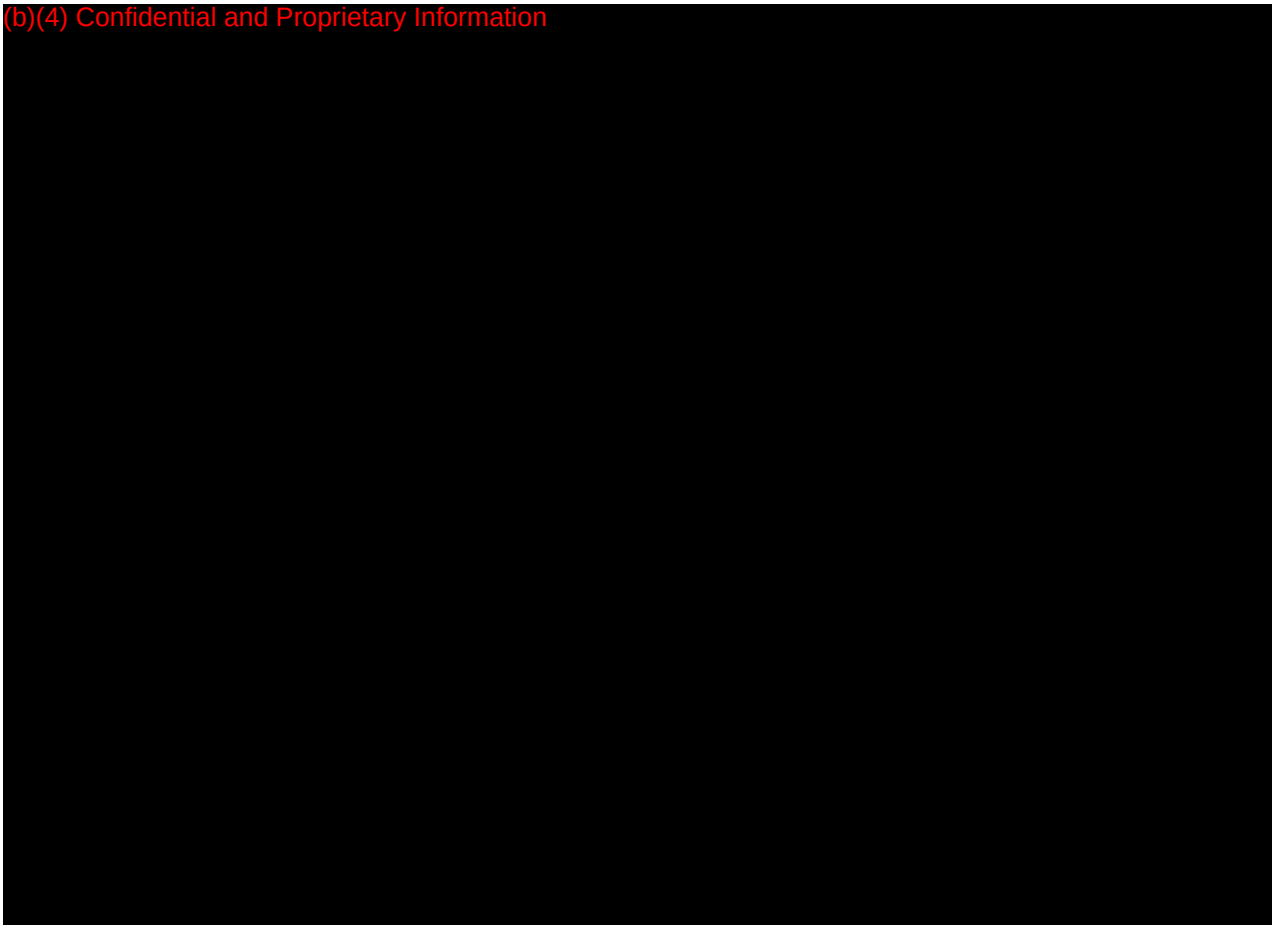
such as observing standard wound healing instructions and to use care with the anatomical location such as avoiding blows to the head.

b. You listed "Dura rupture" among the possible complications. However, the terminology, "Dura rupture" is unclear and not commonly used. Please revise the text to "Unintended durotomy" to improve the readability of your labeling.

The possible complication "Dura rupture" has been changed in the IFU to *Unintended durotomy*.

(b)(4) Confidential and Proprietary Information

[redacted]



The IFU changes described throughout this Additional Information submission give rise to associated changes in other labeling. (b) (4) [redacted] - Master Text, Label OSSDSIGN Cranial PSI, USA, Rev2 conveys packaging label changes that were made to be consistent with the changes to the IFU. (b) (4) [redacted] is provided in redline and blackline versions immediately following the IFU documents.

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MR

4. You provided Magnetic Resonance (MR) Conditional labeling for your device. Several elements are inconsistent with the labeling recommendations in the Guidance for Industry and Food and Drug Administration Staff titled "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" (issued December 11, 2014) and available at http://www.fda.gov/ucm/groups/fdagov-public/%40fdagov-meddev-gen/documents/document/ucm107708.pdf. We believe that consistent labeling for MR Conditional information helps physicians, technologists, and others quickly identify the scanning conditions under which the device can be safely scanned. Please revise your MR Conditional information in the DFU to address the following and provided a red-lined and final clean copy of your revised DFU for our review:

a. Please change the second bullet to "Maximum spatial field gradient of 3000 Gauss/cm (30 T/m)."

The IFU has been edited to reflect this change, and now reads: "Maximum spatial field gradient of 3000 Gauss/cm (30 T/m)." This change and the changes described below are found in (b) (4) - IFU Master Text, OSSDSIGN Cranial PSI, USA, Rev02. Blackline and redline versions are provided.

b. Depending on any updates to your radiofrequency (RF) heating evaluation, please replace the third bullet that begins, "Maximum MR system reported,…" with "Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)."

The IFU has been edited to reflect this change, and now reads: "Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) and head average SAR of <3.2 W/kg (Normal Operating Mode)."

This proposed wording change is responsive to both FDA's items 4.b. and 7.b. (head SAR <3.2 W/kg).

5. Your device is specifically created for a patient's unique anatomical requirements and can therefore be configured for a wide range of clinical needs. (b) (4)

(b)(4) Confidential and Proprietary Information

[redacted]

However, you did not test any other device configurations with clinically realistic sizes and shapes. Your proposed MR Conditional labeling does not limit the scans to device configurations according to your testing. Therefore, please limit your MR Conditional labeling to only those device configurations which were actually tested as the RF-induced heating of device configurations outside of the test samples are unknown.

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Alternatively, please provide RF-induced heating results for all clinically relevant device configurations (or justify the worst-case device configuration) and all scan conditions so that all patients with your device can be scanned safely using Magnetic Resonance Imaging (MRI).

Testing to demonstrate the MRI conditions recommended for Cranial PSI was performed following:

- ASTM F2182 - 11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging, and
- FDA's guidance Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, 2014.
- FDA's guidance Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices, 2016

Testing of the devices was performed on worst-case device configurations and testing consisted of three parts, each with their own report provided in our original submission. The reports in our original submission were not in the proper order and this likely made it difficult to follow the study design. Restating more clearly, the three parts are:

1. (b)(4) Confidential and Proprietary Information [redacted] to find the worst-case device configurations regarding temperature rise.

(b)(4) Confidential and Proprietary Information [redacted]

2. Using the (b) (4) [redacted] results, two worst-case samples were produced and tested in the MR to confirm the validity (b) (4) [redacted].

(b)(4) Confidential and Proprietary Information [redacted]

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- A new report "Validation and Verification Report" of the (b) (4) system is included in this AI#1, starting on page 115. This new report demonstrates the validity (b) (4).

3. (b) (4) define the size limits of configurations which maintain <2 °C temperature rise. These results are embodied in our product specification. We have added an updated version of this report, titled (b) (4) (b)(4) Confidential and Proprietary Information which is attached to this submission as page 149.

- This original report, titled (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information begins on page 720 of our original submission.
- Clinically-relevant sized devices were examined in electromagnetic studies (b) (4) (b) (4)
- The device specification limits allowed a maximum temperature rise of 2 °C.

The design specification limit to maintain <2 °C temperature rise is used internally by OssDsign. Only patient-specific devices that conform to this specification are produced. Non-conforming design requests are rejected. (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information

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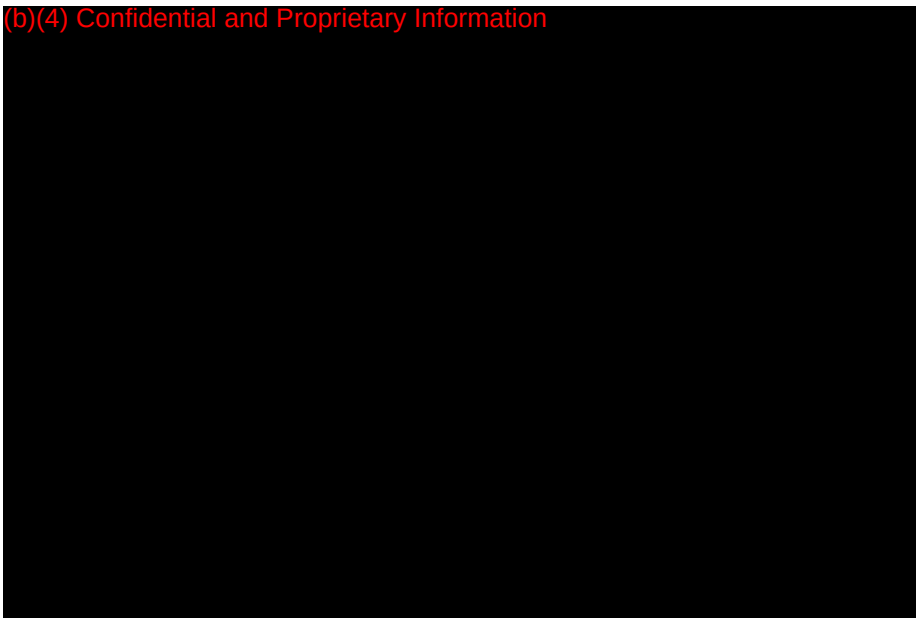
(b)(4) Confidential and Proprietary Information

[redacted]



About our testing methodology:

(b)(4) Confidential and Proprietary Information

[redacted]

6. Your MR Conditional labeling includes compatibility with 3 Tesla (T) MRI scanners. To improve image quality, 3 T MRI usually uses multi-channel transmit coils, i.e., RF shimming. However, your RF-induced heating test results only apply to quadrature transmit coils. Therefore, please change your MR Conditional labeling to allow scanning only for quadrature transmit coils by including an additional bullet point with: "*Quadrature transmit coils only*." Alternatively, please provide RF-induced heating test results for multi-channel transmit coils for all possible amplitude and phase configurations of the individual coil channels to allow patients implanted with your device to have more imaging capabilities.

The MR Conditional Use label in the IFU has been edited to add the condition:

- *Quadrature transmit coils only*

Wording was changed in (b) (4) [redacted] - IFU Master Text, OSSDSIGN Cranial PSI, USA, Rev02. Blackline and redline IFU versions are provided as referenced earlier.

(b)(4) Confidential and Proprietary Information

[redacted]

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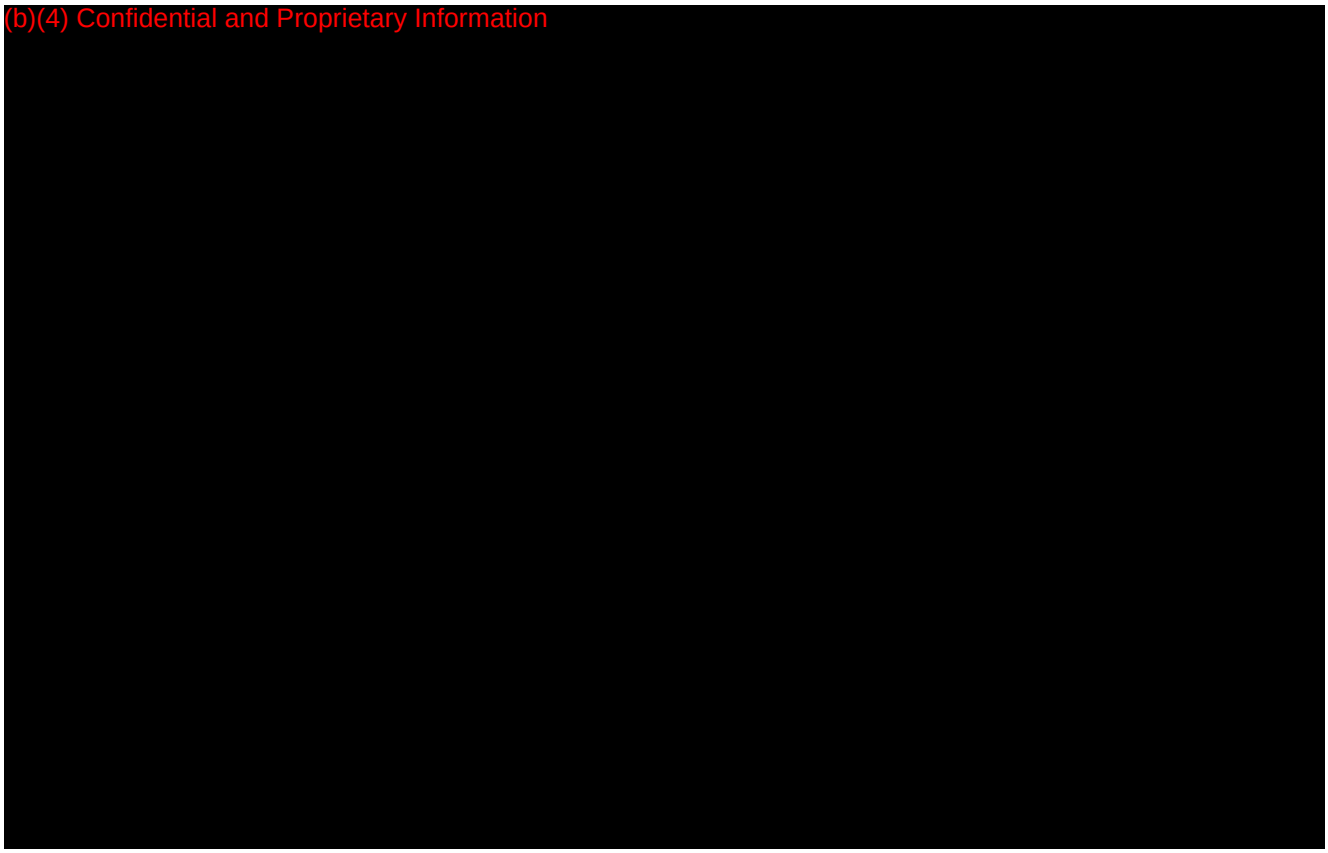
(b)(4) Confidential and Proprietary Information



b. Please be advised that a whole body average of 2 W/kg will result in nearly 6 W/kg in the head. Since the heating effect will depend on the local SAR, the region around the device could heat to unsafe levels. It should be noted that in the Normal level operating mode, the head SAR is controlled to 3.2 W/kg by MRI system software, which may be acceptable for your device. Therefore, please evaluate whether your RF heating safety statement should be modified to read as follows: *"Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg and head average SAR of <3.2 W/kg (Normal Operating Mode)."*

We have adopted FDA's recommend labeling (in item 4.b., above) as the most accurate and clear indication, and included this in our MR Conditional Use statement in our IFU. This labeling is:

- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) and head average SAR of <3.2 W/kg (Normal Operating Mode). Please note that this wording omits the "<" in front of 2 W/kg, as we believe this is redundant with "Maximum".

Our updated MRI Labeling is shown on the following page.

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MRI LABELING

MR Safety Information

MR Conditional

Non-clinical testing and electromagnetic simulations demonstrated that the OSSDSIGN Cranial PSI is MR Conditional. A patient with this device can be scanned safely in an MR system after implantation only subject to the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla
- Maximum spatial field gradient of 3000 Gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) and head average SAR of <3.2 W/kg (Normal Operating Mode)
- Body coil only, do not use head transmit/receive coil
- Quadrature transmit coils only

Under the scan conditions defined above, the OSSDSIGN Cranial PSI is expected to produce a maximum temperature rise of 2˚ C after 15-minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the Cranial PSI extends approximately 7 mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

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(b)(4) Confidential and Proprietary Information

[redacted]

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

(b)(4) Confidential and Proprietary Information

[redacted]

Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017; re-released 10-31-2024 by CDRH under 2024-6423.

9. You did not specify the shelf-life for your device. We believe the expiration for your device is important as your device contains materials that may degrade over time in addition to sterility concerns regarding the package integrity since your device is provided sterile. Please state your proposed shelf-life for the subject device and summarize the supporting evidence for this shelf-life in order to demonstrate substantial equivalence (e.g., package integrity, material stability, performance testing, etc.).

Cranial PSI's one year shelf-life from date of manufacture has been confirmed by testing and reported in (b) (4) [redacted] - Cranial PSI Shelf Life Report. Evidence includes testing of packaging integrity, sterility, material stability and performance with accelerated-aging and real-time aged devices. The Sterility section of the IFU has been updated to: OSSDSIGN Cranial PSI is delivered sterile *and is confirmed to remain sterile for one year from date of manufacture*.

(b)(4) Confidential and Proprietary Information

[redacted]

OssDsign indicates on the Patient Label that the Last Day of Use (shelf life) is twelve months following manufacture. OssDsign indicates in the IFU and Informative Label that *For best results, implant within six months from date of manufacture*.

The Patient Label has been updated and is provided in (b) (4) [redacted] Master Text, Label OSSDSIGN Cranial PSI, USA, Rev2. Other label changes were made to be consistent with the changes to the IFU that were previously described in this Additional Information submission. Redline and blackline versions are provided, as previously referenced.

10. You reported that the level of endotoxin is monitored to ensure acceptable level and stability in production facilities in (b) (4) [redacted] *Validation of Production Facilities, Environment*. However, you do not specify the endotoxin specification required for Cranial PSI devices. The endotoxin release specification for cerebral spinal fluid (CSF) contacting devices with a neurological indication is < 2.15 EU/device, as discussed in FDA's Guidance for Industry, "Pyrogen and Endotoxin Testing: Questions and Answers" issued June 2012 and available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM310098.pdf. Therefore, please report the required endotoxin for the cranial PSI devices. In addition, please report the required endotoxin for the Cranial PSI devices. In addition, please provide the routine batch release procedures followed to ensure each lot of your device conforms to the required < 2.15 EU/device endotoxin lot release specification.

Specification:
The finished Cranial PSI device conforms to the required endotoxin release specification

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< 2.15 EU/device for long-term cerebral spinal fluid (CSF) contacting devices with a neurological indication.

Endotoxin management procedures are controlled by five OssDsign documents. These are described below, and include:

(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

Biocompatibility

11. You provided biocompatibility data from tests conducted on a representative piece of your Cranial PSI device. Your device generally met the acceptance criteria for the various tests you conducted; however, the following concerns should be addressed before this data can be determined to be adequate:

(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

c. (b)(4) Confidential and Proprietary Information
(b) (4) In the case of the sensitization assay, this was only (b) (4)
(b) (4) it was observed in (b)(4) Confidential and Proprietary Information
tests. (b)(4) Confidential and Proprietary Information
(b) (4)
(b)(4) Confidential and Proprietary Information
does not raise biocompatibility and safety concerns regarding the clinical use of your device.

(b)(4) Confidential and Proprietary Information
(b)(4) Confidential and Proprietary Information ot consistent with clinical use. This conclusion is further justified by OssDsign's Exhaustive Extraction Chemical Analysis which shows no agents of concern and OssDsign's post-market surveillance data which shows no clinical incidents of concern.

Additional details on this topic were previously communicated by OssDsign to FDA in Q161165 on 12Jul16, and are repeated below:

(b) (4) associated with the clinical use of the Cranial PSI.

(b)(4) Confidential and Proprietary Information

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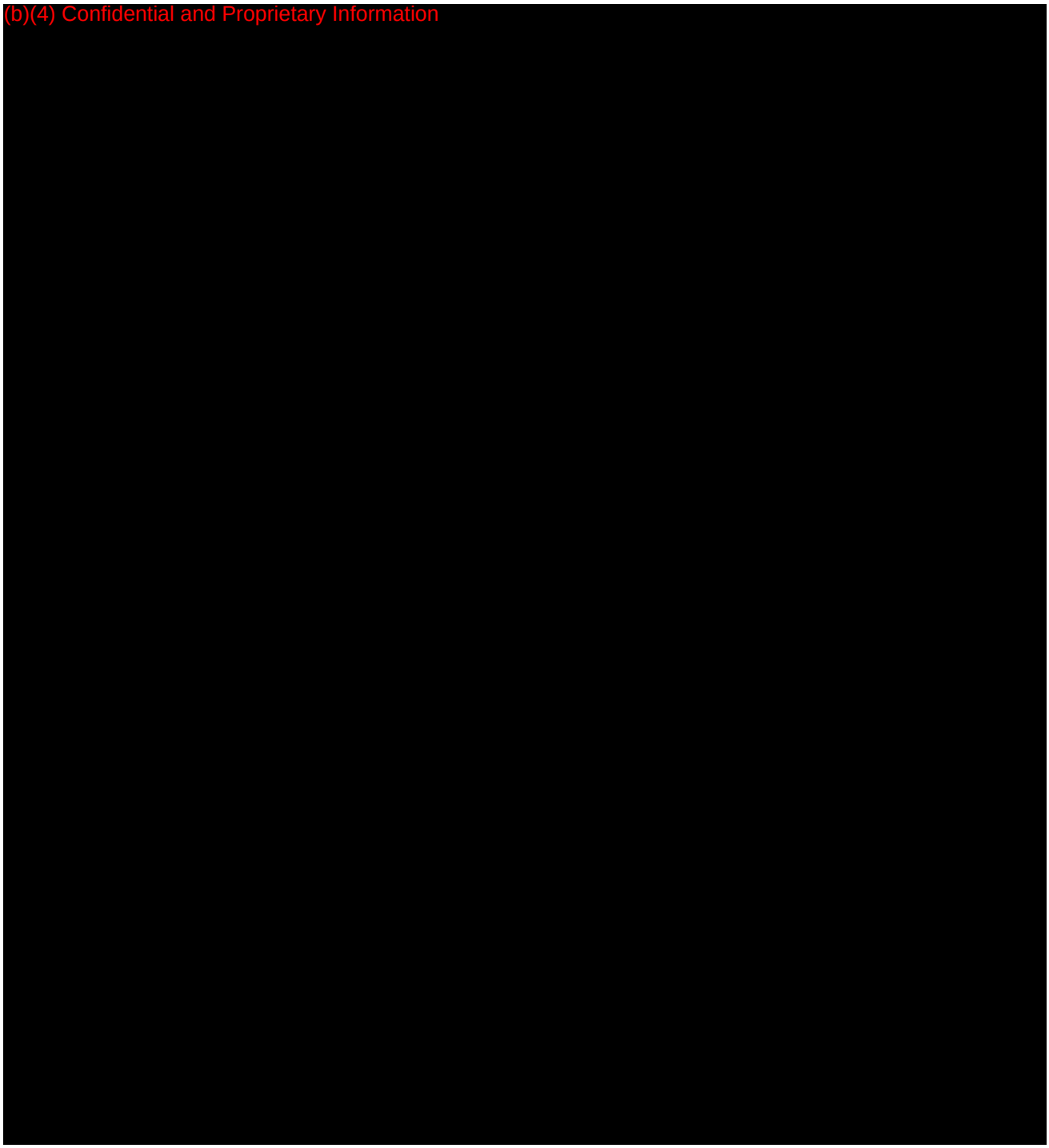

User instructions to make adjustments to fit are provided in the IFU and include:

a. Fastening arms may be gently adjusted to improve the fit.
b. OSSDSIGN Cranial PSI is carefully designed to fit a specific patient's unique defect. If the surgeon desires to modify the fit, bone must be removed from the patient defect using standard surgical procedures. Do not remove material from the OSSDSIGN Cranial PSI. No cutting or reshaping of the device is permitted. For best results, implant within six months from date of manufacture.

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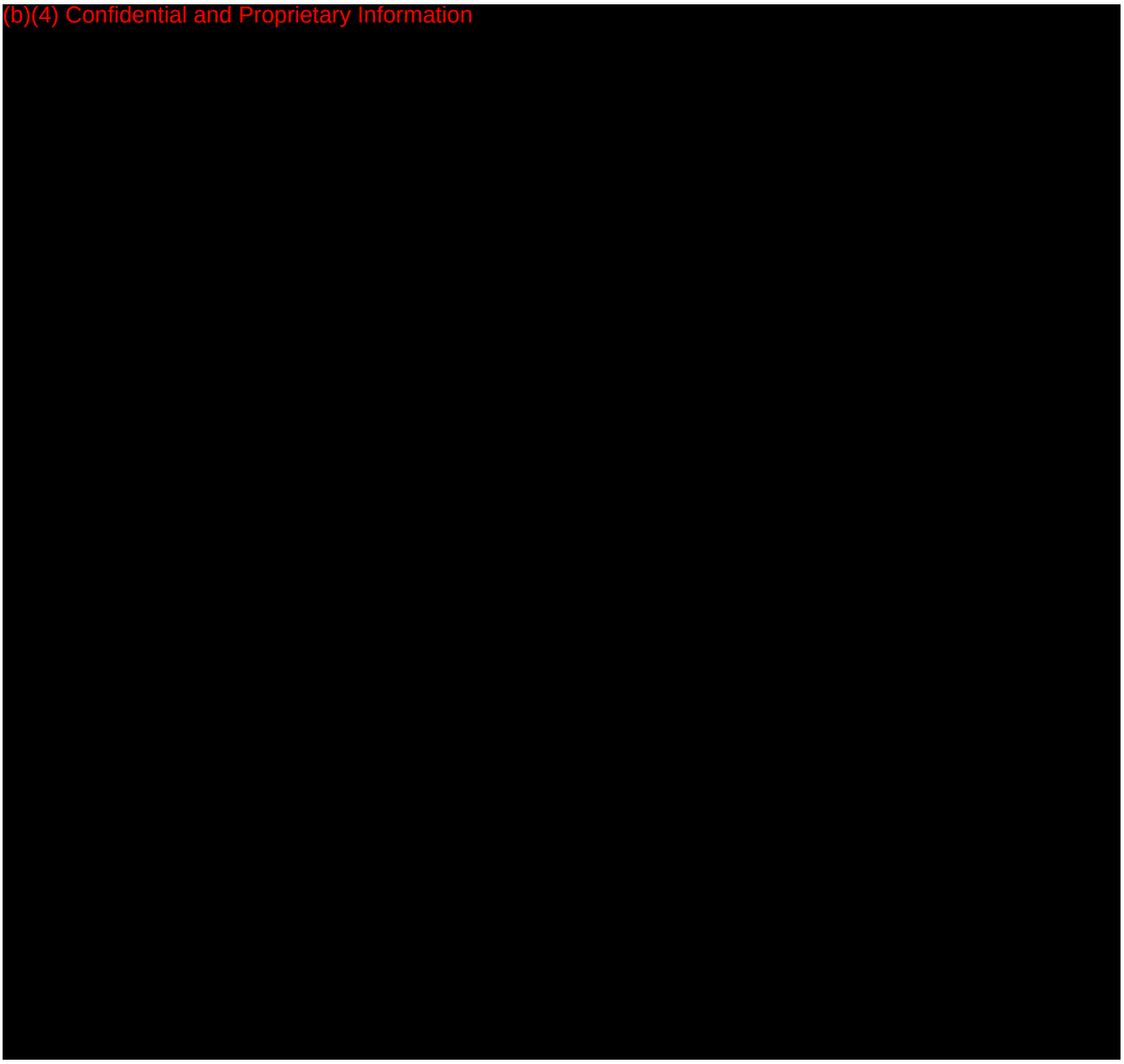
(b)(4) Confidential and Proprietary Information

[redacted]



3. Explain how the characteristics of the OssDsign implant differ from the predicate device such that adjustments are generally not needed as claimed on page 16 in Q161165.

OSSDSIGN Cranial PSI differs from its predicate in that:

a. The predicate device is not additively manufactured.
b. The predicate device does not have easily adjustable fastening arms, which are more precisely controlled than modifications to perforated plate.
c. The predicate device does not have production tolerances <1 mm.

OSSDSIGN Cranial PSI Directions For Use limit the patient-specific device design to a CT data set that is not older than six months from date of order and recommends implantation not later than six months from date of manufacture. This characteristic of the subject device is a key difference compared to the predicate device, KLS Martin

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PCI Titanium Mesh. Additionally, OSSDSIGN Cranial PSI fastening arms and titanium mesh provide a degree of flex to the device that assists the surgeon in achieving a proper fit.

(b)(4) Confidential and Proprietary Information

B. Describe the potential and avoidance of ceramic fractures to the device during implantation

Ceramic fractures are unlikely during implantation. The Cranial PSI has been designed so that loads applied to the device are transferred to the additively manufactured titanium mesh. Thereby, the strain on the ceramic is limited and the risk of fracture minimized. This result is confirmed by the performance testing provided in our premarket submission. If a ceramic fracture does occur, the device performance is not affected because all performance claims are derived from the titanium mesh. No fractures during implantation have been reported in clinical use with the subject device. (b) (4)

(b)(4) Confidential and Proprietary Information

C. Provide evidence to support these claims

The following evidence is provided in support of these claims:

- Exhaustive Extraction Chemical Analysis shows no agents of concern, see page 221 of this submission
- Post-market surveillance data shows no incidents of concern, see page 242 of this submission
- The titanium mesh provides all the device mechanical performance and no alterations to the titanium mesh are permitted or necessary
- The device was shown to be biocompatible in testing with intentionally generated particles (provided in our premarket submission) and with additional conforming Pyrogenicity and Hemolysis testing results requested by FDA which are provided on page 303 of this Additional Information submission.

12. Your device is a permanent implanted device with tissue/bone and indirect blood contact through reabsorption of CSF into the venous system. Although your device utilizes commonly used materials, the biocompatibility of a device depends not only on

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the materials used but also on the processing of the materials, manufacturing method (including the cleaning and sterilization process), and manufacturing residuals that may be imparted on the final device (i.e., contaminants, such as additives, coolants, detergents, or any other processing aid that could adversely change or affect final composition or safety of the device). You have not conducted all of the testing recommended for your device according to ANSI/AAMI/ISO 10993-1:2009 (R2013) *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process* and the FDA's Blue Book Memorandum G95-1. Due to contact with CSF, please conduct indirect hemolysis and material-mediated pyrogenicity testing using the final, sterilized worst case representative device, with justification for the selection of representative devices. Additionally, subchronic and chronic systemic toxicity should be addressed. Subchronic toxicity and chronic toxicity may also be addressed as part of an implantation study at a clinically relevant site by including multiple time points and evaluation of appropriate endpoints or by including appropriate risk assessments for toxicity after an exhaustive chemical characterization study using your worst case representative device.

(b)(4) Confidential and Proprietary Information [redacted]

The following FDA requested studies have been completed with satisfactory results and are conveyed in this Additional Information response:

- Indirect hemolysis testing – (b)(4) Confidential and Proprietary Information [redacted] (b)(4) Confidential and Proprietary Information [redacted]
- Pyrogenicity testing – (b)(4) Confidential and Proprietary Information [redacted] (b) (4) [redacted]
- Exhaustive Extraction Chemical Analysis – (b)(4) Confidential and Proprietary Information [redacted] (b)(4) Confidential and Proprietary Information [redacted]

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(b)(4) Confidential and Proprietary Information [redacted]

Further, in the Q161165, 9Aug16 revised meeting minutes, FDA advised that OssDsign:

A. Device is categorized as CSF communicating for biocompatibility testing and endotoxin release requirements

Agreed.

B. DFU inclusion of a surgical drain is beneficial but not sufficient to acceptably reduce risk

Agreed.

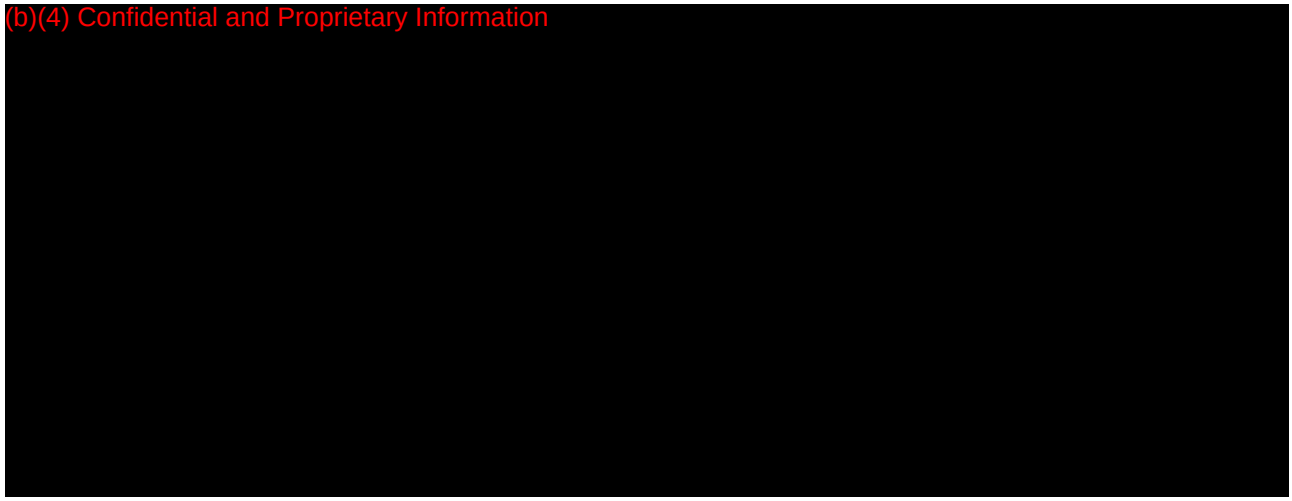
C. Indirect hemolysis and Material-mediated pyrogenicity test results are needed

Completed, see page 303.

D. As stated in the K161090 Deficiency List we sent on June 17, 2016, subchronic and chronic systemic toxicity of your permanent implant device should be addressed by testing, or as part of an implantation animal study at a clinically relevant site using multiple time points and evaluation of appropriate endpoints, or by including appropriate toxicological risk assessments for systemic toxicity after an exhaustive chemical characterization study using a "worst case" final finished device. If chemical characterization is used, the following should be addressed:

1. Justification of porosity calculations used to determine the extraction ratio, solvents/extraction vehicles used (non-polar, mid polarity, polar), exhaustive extraction methods, and selection of analytical methods.

(b)(4) Confidential and Proprietary Information [redacted]



2. Risk assessment based on CSF communication

No subchronic and chronic systemic toxicity risk has been identified by our Post-market Surveillance Study, recent Pyrogenicity and Hemolysis studies and Exhaustive

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Extraction Chemical Analysis.

(b)(4) Confidential and Proprietary Information

OssDsign searched for a normative reference for allowable limits of substances in CSF, and found (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

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OssDsign scientific assessment of potential health risks from Cranial PSI chemical residuals found that none of the detected residuals pose a patient risk. As seen in Table 2., above, the Exhaustive Extraction Chemical Analysis detected only elements and substances naturally occurring in the human body.

(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

3. Post-market surveillance data, as outlined in Question 3.C., below.

This response is provided in section 13 b, below.

13. You have previously received recommendations from the FDA regarding the Cranial PSI device in two related Pre-Submissions (Q150051 and Q150051/S001) that have not been addressed in your current submission. Please provide the following or justify omitting this data:

a. A test report describing qualitative and quantitative chemical residuals analysis (i.e., exhaustive extraction) on the final, sterilized Cranial PSI device that represents "the worst case" from a material residual perspective, and includes the following:

(b)(4) Confidential and Proprietary Information

[redacted]

ii. Evaluation of the particle composition and size distribution that is extractable

CSID sign Confidential

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from the additive manufactured finished device.

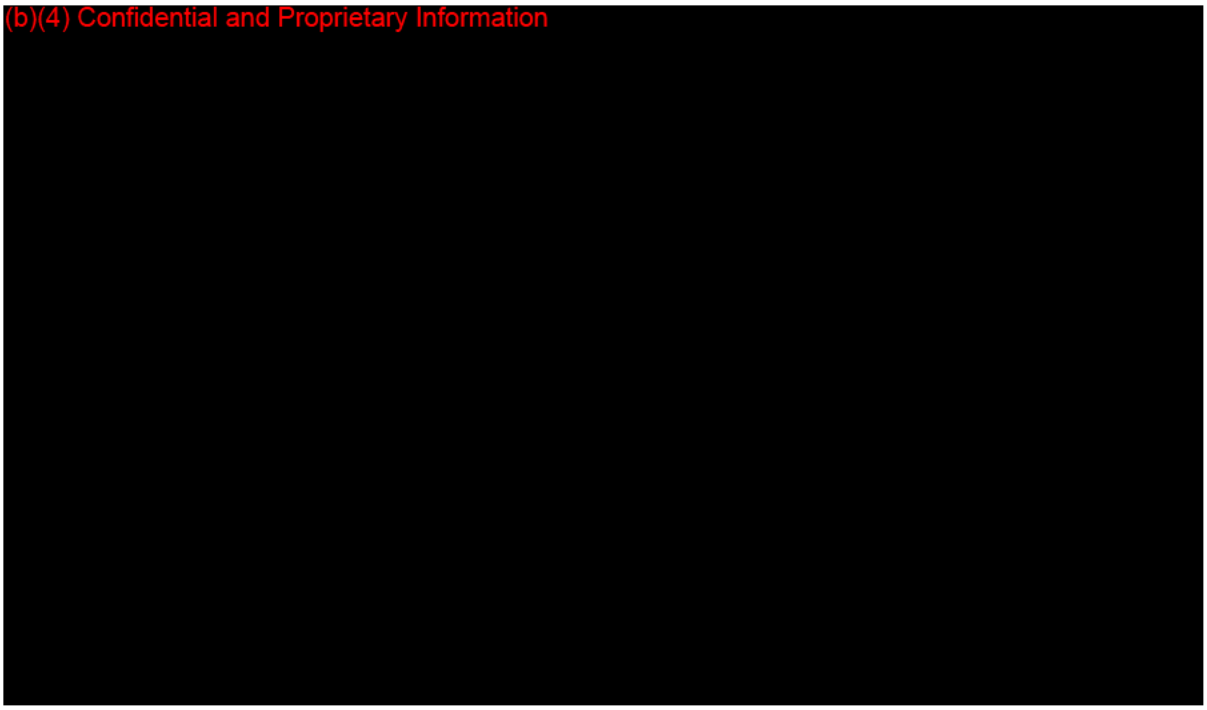
Complete. Please see 12.D.2, Table 2, above and our Exhaustive Extraction Chemical Analysis (b) (4) on page 221. The particle size distributions ranges presented in the report (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information (b)(4) Confidential and Proprietary Information are not titanium. This is confirmed by the results from the (b) (4) analysis where (b) (4) (b) (4) were the main residues found in the water extract with no detection of (b) (4)

iii. A toxicological risk analysis on the chemicals and particles identified and quantified in the residuals extraction study.

Please see our response in 12.D.2, above.

b. According to FDA's Blue Book memorandum G95-1, an implantation test is recommended for your device, which is a permanent implant with tissue/bone contact. ISO 10993-6 (*Biological Evaluation of Medical Devices – Tests for Local Effects After Implantation*) recommends that the implantation study should be conducted at a clinically relevant implant site to assess the local tissue response. Also, the standard recommends that for degradable/resorbable materials, the local tissue response shall be evaluated at various time points including the time point when there is no or minimal degradation, the time point when degradation is taking place and the time point when a steady state has been reached. Thus, unless justified otherwise, please provide implantation study data (using a clinically relevant site) on your device with a justification for the choice of the device size for the implantation study and the time points selected for evaluation.

(b)(4) Confidential and Proprietary Information



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(b)(4) Confidential and Proprietary Information

"4. **Executive Summary**

OSSDSIGN Cranial PSI has been successfully used in (b) (4)
(b)(4) Confidential and Proprietary Information

Group Data including all Cranial PSI devices shows (b)(4) Confidential and Proprietary
(b)(4) Confidential and Proprietary Information
(b)(4) Confidential and Proprietary Information All complications
were determined to be not device related except for one. (b) (4)
(b)(4) Confidential and Proprietary Information
This was done in contradiction to Cranial PSI Instructions For Use.

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Performance Testing

(b)(4) Confidential and Proprietary Information

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(b)(4) Confidential and Proprietary Information

[redacted]

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(b)(4) Confidential and Proprietary Information

[redacted]

OssDsign has removed the bioactivity claim from our submission.

Promotional Material

Claims and labeling have changed since the original 510(k) submission. (b) (4) [redacted] - Promotional Material, OSSDSIGN Cranial PSI provides updated promotional material starting on page 327.

-end-

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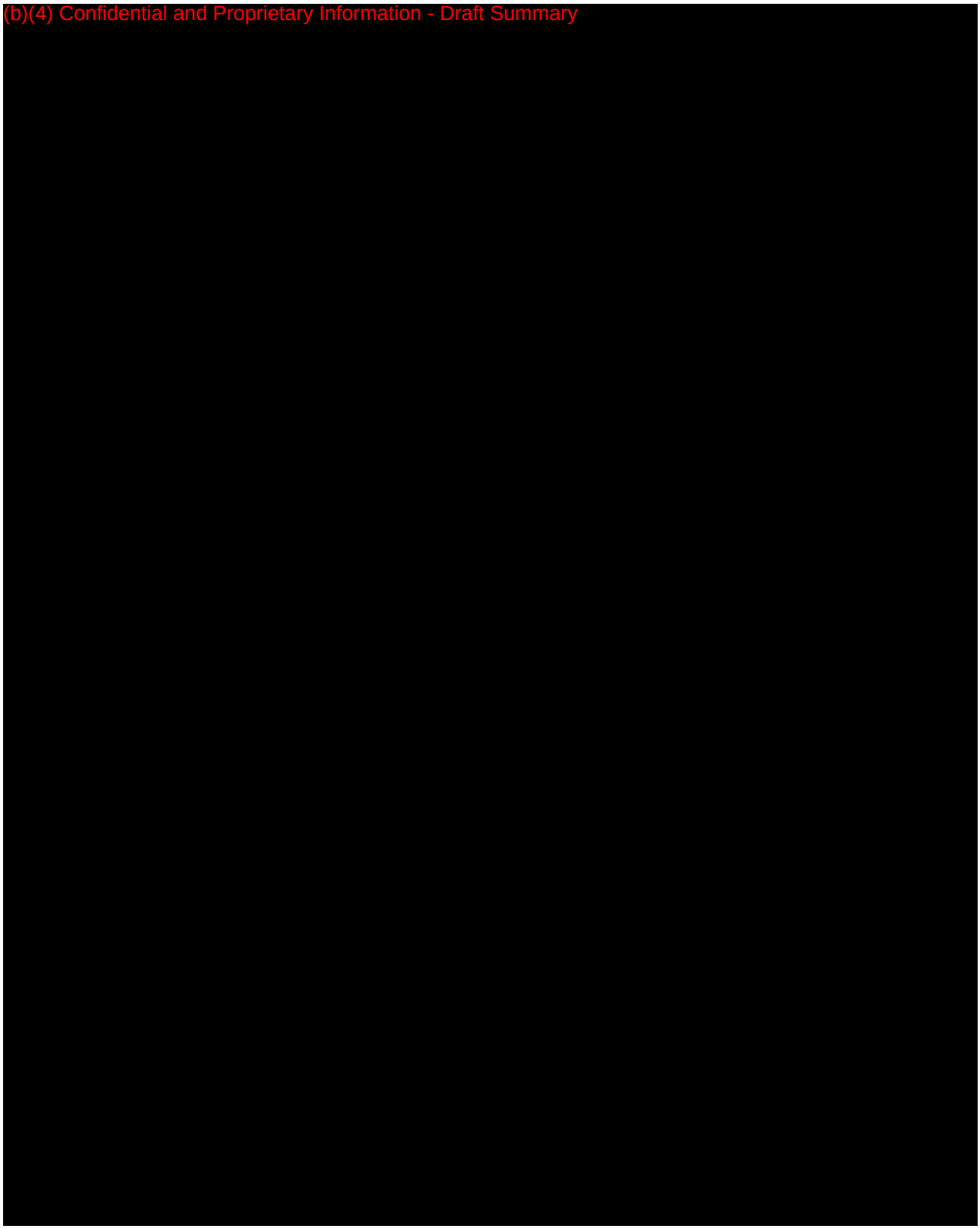
510(k) SUMMARY

K161090

(b)(4) Confidential and Proprietary Information - Draft Summary



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

(b)(4) Confidential and Proprietary Information - Draft Summary

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Performance Standards and Regulations, OSSDSIGN Cranial PSI

OSSDSIGN Cranial PSI complies with the following standards.

Standard	Title	Verified in
ASTM		
ASTM F136-13	Standard Specification for Wrought Titanium-(b) (4) (b) (4) for Surgical Implant Applications	Materials tests,
ASTM D4169-09	Standard practice performance testing of shipping containers and systems	Shipping test
ASTM F1929-12	Standard test method for detecting seal leaks in porous medical packaging by dye penetration	Packaging test
ASTM F1980-07	Standard guide for (b) (4) aging of sterile barrier	Packaging test
ASTM F88	Standard test method for seal strength if flexible barrier	Packaging test
ISO		
Din ISO 9277-2014	Determination of the (b) (4) of solids (b) (4)	(b) (4)
ISO 15223-1	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	Label
ISO 17665	Sterilization of health care products, Moist heat	Sterility validation
EN-ISO 13485- 2012	Medical Devices - Quality management systems - Requirement for regulatory purposes	OssDsign Quality system
ISO 14971-2012	Medical Devices – Application of risk management to medical risk	Hazard Analysis
EN-ISO 10993	Biological evaluation of medical devices	Material tests, (b) (4)

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			(b)(4) Confidential and Proprietary Information
ISO 11737-2	Sterilization of medical devices – Microbiological methods – Test of sterility performed in the, definition, validation and maintenance of a sterilization process	Sterility validation	
ISO 13175-3	Implants for Surgery- (b) (4) (b)(4) Confidential and Proprietary Information	Material testing, trace metals	
USP			
USP 71	Sterility tests	Sterility controls	
USP 85	Bacterial endotoxin tests	Endotoxin testing	
USP 161	Medical Devices - Bacterial endotoxin and pyrogen tests	Endotoxin testing	

Note: This list is an extract from (b) (4) Documents List, for standards relevant to Cranial PSI.

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

Department of Health and Human Services **(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

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

ASTM F136-13 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	[X]	[ ]
FDA Recognition number [3] # 8-377		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	[X]	[ ]
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	[X]	[ ]
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	[X]	[ ]
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	[X]	[ ]
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	[ ]	[X]
Were there any deviations or adaptations made in the use of the standard?	[ ]	[X]
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	[ ]	[ ]
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	[ ]	[X]
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	[ ]	[X]
Is there an FDA guidance [6] that is associated with this standard?	[ ]	[X]
If yes, was the guidance document followed in preparation of this 510k?	[ ]	[ ]

Title of guidance: _____

[1] The format ing conven ion for the title is: [SDO] [numeric iden ifier] [title of standard] [date of publication]

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

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

[4] The summary report should include: any adaptations used to adapt to he 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 he name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional informa ion 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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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

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

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM D4169-09 Standard Practice for performance Testing of Shipping Containers and Systems

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-300	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM D4169-09 Standard Practice for performance Testing of Shipping Containers and Systems

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2	Significance and use	☒ Yes ☐ No ☐ N/A
(b)(4) Confidential and Proprietary Information		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Schedule A- Handling - manual and Mechanical	☒ Yes ☐ No ☐ N/A
(b)(4) Confidential and Proprietary Information		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

Department of Health and Human Services **(To be filled in by applicant)**

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

ASTM F1929-12 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	[X]	[ ]
FDA Recognition number [3] # 14-578		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	[ ]	[X]
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	[X]	[ ]
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	[X]	[ ]
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	[X]	[ ]
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	[X]	[ ]
Were there any deviations or adaptations made in the use of the standard?	[ ]	[X]
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	[ ]	[ ]
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	[ ]	[X]
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	[ ]	[X]
Is there an FDA guidance [6] that is associated with this standard?	[ ]	[X]
X If yes, was the guidance document followed in preparation of this 510k?	[ ]	[ ]

Title of guidance: _____

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

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1929-12 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Procedure	[X] Yes [ ] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Methods selection

(b)(4) Confidential and Proprietary Information

[redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		[ ] Yes [ ] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		[ ] Yes [ ] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

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

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F-1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-229	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F-1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-283	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.1	Significance and Use	☒ Yes ☐ No ☐ N/A

(b)(4) Confidential and Proprietary Information

[redacted]

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] [ ] Special Abbreviated

STANDARD TITLE [1] ISO9277 Determination of the specific surface area of solids by gas adsorption - BET method

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

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 9277 Determination of the specific surface area of solids by gas adsorption -- BET method

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Procedure	[X] Yes [ ] [ ] No

(b)(4) Confidential and Proprietary Information

[redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		[ ] Yes [ ] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		[ ] Yes [ ] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

Department of Health and Human Services **(To be filled in by applicant)**

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1] ISO 15223-1 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	[X]	[ ]
FDA Recognition number [3] # 5-90		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	[ ]	[X]
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	[X]	[ ]
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	[X]	[ ]
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	[X]	[ ]
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	[ ]	[X]
Were there any deviations or adaptations made in the use of the standard?	[ ]	[X]
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	[ ]	[ ]
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	[ ]	[X]
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	[ ]	[X]
Is there an FDA guidance [6] that is associated with this standard?	[ ]	[X]
If yes, was the guidance document followed in preparation of this 510k?	[ ]	[ ]

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 17665-1 Sterilization of Health Care Products, Moist heat

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-261	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 17665-1 Sterilization of Health Care Products, Moist heat

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Process definition	☒ Yes ☐ No ☐ N/A

(b)(4) Confidential and Proprietary Information

[redacted]

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

Department of Health and Human Services **(To be filled in by applicant)**

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

ISO 13485 Quality Management Systems - Requirements for regulatory purposes, 2012

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

STANDARD TITLE
ISO 13485 Quality Management Systems - Requirements for regulatory purposes, 2012

CONFORMANCE WITH STANDARD SECTIONS*

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

(b)(4) Confidential and Proprietary Information

[redacted]

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

ISO 14971 Medical devices- Application of risk management to medical risk, July 2013

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE	

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

Department of Health and Human Services **(To be filled in by applicant)**

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

ISO10993 Biological evaluation of medical devices 2009

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	[X]	[ ]
FDA Recognition number [3] # 2-156		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	[X]	[ ]
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	[X]	[ ]
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	[X]	[ ]
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	[ ]	[X]
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	[X]	[ ]
Were there any deviations or adaptations made in the use of the standard?	[ ]	[X]
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	[ ]	[ ]
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	[ ]	[X]
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	[X]	[ ]
Is there an FDA guidance [6] that is associated with this standard?	[X]	[ ]
If yes, was the guidance document followed in preparation of this 510k?	[X]	[ ]

Title of guidance: Q161165

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

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

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO10993 Biological evaluation of medical devices 2009

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative references	☒ Yes ☐ No ☐ N/A

(b)(4) Confidential and Proprietary Information

[redacted]

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11737-2 Sterilization of Medical Devices – Microbiological methods Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-327	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

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

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11737-2 Sterilization of Medical Devices – Microbiological methods Part 2: Test of sterility performed in the definition, validation and maintenance of a sterilization process.

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

Department of Health and Human Services **(To be filled in by applicant)**

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

ISO13175-3 Implants for surgery - Calcium Phosphate Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes

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

Title of guidance: _____

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

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO13175-3 Implants for surgery - Calcium Phosphate Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1.	Trace elements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

(b)(4) Confidential and Proprietary Information

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2-4.6		☐ Yes ☐ No ☐ N/A

❖

(b)(4) Confidential and Proprietary Information

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

Department of Health and Human Services **(To be filled in by applicant)**

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

USP 71 - Sterility tests

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

Title of guidance: _

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
USP 71 - Sterility tests

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Test for sterility of the product to be examined	[X] Yes [ ] No [ ] N/A

(b)(4) Confidential and Proprietary Information

[redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		[ ] Yes [ ] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		[ ] Yes [ ] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services **(To be filled in by applicant)**

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TYPE OF 510(K) SUBMISSION

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

USP 85 – Bacterial Endotoxin Test

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

Title of guidance: Pyrogen and Endotoxins Testing: Questions and Answers, June 2012

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

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
USP 85 – Bacterial Endotoxin Test

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Photometric quantitative techniques	☐ Yes ☐ No ☒ N/A

(b)(4) Confidential and Proprietary Information

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
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Records processed under FOIA Request # 2017-1437, released by CDRH on 8-21-2017, re-released to 3-1-2024 by CDRH under 2024-6423
Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

Department of Health and Human Services **(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

[X] Traditional [ ] Special [ ] Abbreviated

STANDARD TITLE [1]

USP 161 Medical Devices - Bacterial endotoxin and pyrogen tests

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

Title of guidance: _____

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

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

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

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

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

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE	

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
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