Hi Sean,
I have reviewed and accept the changes proposed below to the 510(k) summary.

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Friday, January 19, 2024 2:28 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 5:21 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510 (k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

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Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

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From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Sent: Friday, December 29, 2023 7:15 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>

Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 10/31/2023 7:36:27 PM
To: jayasri.prabakaran@si-bone.com
CC: DCCLetters@fda.hhs.gov
Subject: K233508 Acknowledgement Letter
Attachments: K233508-Acknowledgement Letter.pdf

October 31, 2023

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

The CDRH Portal is now available:
Instead of shipping your submissions to us, you can now upload them at our CDRH Portal.

*** This is a system-generated email notification ***

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgement Letter

10/31/2023

Jayasri Prabakaran, Associate Director, Regulatory Affairs
Si-Bone, Inc.
471 El Camino Real, Suite 101
Santa Clara, CA 95050
UNITED STATES

Dear Jayasri Prabakaran:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K233508
Received: 10/31/2023
Applicant: Si-Bone, Inc.
Device: iFuse Bedrock Granite Implant System (Multiple)

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

ATTACHMENT 14B

510(k) Summary

In accordance with 21 CFR 807.92, a separate, stand-alone 510(k) Summary is provided herein.

510(k) SUMMARY

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIB
WO66 RM4422
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: December 21, 2023

Reviewer: Sean Miller

510(k)# K233508 Subject: Traditional

Applicant: Si-Bone, Inc.	**Device Trade Name:** iFuse Bedrock Granite Implant System (Multiple)
Contact Name: Jayasri Prabakaran	**Contact Title:** Associate Director, Regulatory Affairs
Correspondent Firm: Si-Bone, Inc.	**Phone:** (b)(6) **Email:** jayasri.prabakaran@si-bone.com
Received Date: October 31, 2023	**Due Date:** January 29, 2024
Pro Code(s): OUR, NKB, OLO **Class:** II **Reg #:** 888.3040	**Reg Name:** Smooth Or Threaded Metallic Bone Fixation Fastener

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K222774	OUR, NKB, OLO	iFuse Bedrock Granite® Implant System	SI-BONE, Inc.
K223494	NKB, KWP, KWQ, HBE, OLO	CD Horizon Spinal System	Medtronic
K223273	NKB, KWP, KWQ	ASTRA Spine System	SpineCraft, LLC

Recommendation

(b)(5)

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(b)(5)

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(b)(5)

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.16.03)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
For each of the specific issues identified in the recommended requests to the applicant above, I and/or if applicable contributing consulting reviewer(s) (and or supervisors), have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability for requests: add all relevant numbers here, else delete that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s). I also confirm, if applicable, that contributing consulting reviewers (and or supervisors) have provided the above attestation.	
Reviewer Sign-Off	Sean Miller -S Digitally signed by Sean Miller -S Date: 2023.12.28 16:44:50 -05'00'

Hi Jai,

No, this should be our only question.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>

Sent: Thursday, January 18, 2024 3:10 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov>

Cc: K233508@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Thank you, Sean. Appreciate your quick response. We will review the IFU updates and get back to you.

Can you please let us know if this the only question or are we expecting more questions later today?

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1ts6TqLk1xb1HVITB_Bl5hZp3Ipq32xmdGrBFVXQjoZ0-XuOV3PoN2gV58BLN-5f40IYOsuFjuz6Wk7bYUJwwhrNXkjyVZZyKrvVqm-rFXNEu2UUWKDMvQM2J3mh5Zs3OFCgvNXDjeOTz570L_bQp-W0tpe-cAhW9Mpm0kV_nWZ6Xx_nKlVRC13ISm4hu2r1n_5bfYxIbw6egWMEq0IV3pQ/http%3A%2F%2Fwww.SI-BONE.com>

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www.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

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510(k) SUMMARY

iFuse Bedrock Granite® Implant System

I. 510(k) SUBMITTER

SI-BONE, Inc.
471 El Camino Real, Suite 101,
Santa Clara, CA 95050
Phone: 408-207-0700
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Contact Person: Jayasri Prabakaran, Associate Director, Regulatory Affairs

FDA Establishment
Registration No.: 3007700286

Date Prepared: January 18, 2024

II. DEVICE

Trade Name of Device	iFuse Bedrock Granite® Implant System
Classification Name	Sacroiliac Joint Fixation
Classification	II
Regulation Number	21 CFR 888.3040; Smooth or threaded metallic bone fastener 21 CFR 888.3070, Thoracolumbosacral pedicle screw system 21 CFR 882.4560, Stereotaxic instrument
Product Code	OUR, NKB, OLO

III. PREDICATE DEVICES

Primary Predicate:

Predicate Device	Manufacturer	510(k)#	Clearance Date
iFuse Bedrock Granite Implant System	SI-BONE, Inc.	K222774	December 22, 2022

Additional Predicates:

Predicate Device	Manufacturer	510(k)#	Clearance Date
CD Horizon Spinal System	Medtronic Sofamor Danek	K223494	January 23, 2023
SpineCraft, LLC	SpineCraft, LLC	K223273	December 22, 2022

IV. DEVICE DESCRIPTION

The iFuse Bedrock Granite® Implant System consists of implants of various lengths and diameters, and associated instruments sets. Instrument sets are provided for both open and minimally invasive approaches. The titanium (Ti-6Al-4V ELI) implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the iliac trajectories. Additionally, iFuse Bedrock Granite can be placed into the S1 pedicle. The device is designed for connection to commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm titanium alloy or cobalt chrome alloy spinal fixation rods.

V. INDICATIONS FOR USE

The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
• To augment immobilization and stabilization of the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse

Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

VI. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The subject device is substantially equivalent to its predicate in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. The differences in the indication for use statement from the previously cleared legally marketed predicate are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, iFuse Bedrock Granite Implant System is substantially equivalent to its predicate device.

VII. PERFORMANCE DATA

SI-BONE performed the following performance tests:

- Static and Dynamic Cantilever Testing per ASTM F2193
- Post-Fatigue Sleeve Dissociation Testing
- Static Torsion Testing per ASTM 543
- Static Axial Pull out Testing per ASTM 543
- Characterizing the Porous Surface Bedrock Granite Test (Static Shear, Shear Fatigue, Static Tensile, Abrasion Properties)
- Construct Testing per ASTM F1717 (Static and Dynamic Compression Bending, Static Torsion)

The test results demonstrate that the device is substantially equivalent to the predicate device.

VIII. CONCLUSION

The modified iFuse Bedrock Granite implant (reduced diameter and length) is substantially equivalent to its predicate in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. Testing has shown substantially equivalent benchtop performance. The differences in the indication for use statement from previous cleared legally marketed predicates are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Test results demonstrate that the device is substantially equivalent to the legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

Hi Jai,

Unfortunately I do not have a definitive answer on that for you at this time. I have forwarded your question to our program staff, and I will relay their response to you once they have discussed it internally (likely sometime next week). Regardless, the final decision for this submission will be processed shortly.

Thank you for your patience,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>

Sent: Thursday, January 25, 2024 4:16 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov>

Cc: Daniel Cher <DCher@si-bone.com>; K233508@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

(b)(4)

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1uZf64yMUekSKzt3D7_RiVNB3V3XchDEvA908zNdB6iCRxZI3zFvkdeBvmcs-cTEQRZumPHDN-79EaRcBOi7CGboYoO3rWs0bgyWgU8Gsz0vo_LrwYM7TD1uBP7p_cuiAA1Z8iAcIKsD2Iqe8f5ppQ04OKTca25LRzpyTAkeU8o0B1kbUFzEHYWqH0ExqTFwrKn65zek6ZoVg2PC3HMo1GQ/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 25, 2024 12:15 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>;
K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

(b)(4)

Please confirm by COB today (1/25/2024) that you acknowledge this email that (b)(4) does not apply to the current submission (K233508).

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Tuesday, January 23, 2024 5:11 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

Appreciate this update. Thank you.

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1jWeP7iOdiTzaL9AZyaq9h_HyUod_5GVR59T01yfxcJWpb7adv86YUMSOmq7v7vU6-KW4rPG35pxKkzuJReOtqEpG7Wa1e8V1VPUiXO_DlM7vpw-MlUQbOxB8EOOEm61g4RUwu0rOaiiKhBudjk_MSR0SxELLXx9ckPF60c3TTfZBUhlq-ms_ZduANgMJ6JF7luv0DxfQbj3MQvC1aSQyLA/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Tuesday, January 23, 2024 2:07 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

We are currently finalizing our review. While I can't give an exact date on the decision, we do not believe it will be too much longer. If we need anything more from you I'll be sure to contact you,

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Tuesday, January 23, 2024 11:11 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

Hope you had a good weekend. Our team is curious to know if a decision will be made by this week. So please let me know if any other information is needed from our end.

Thanks again for your timely review!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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www.SI-BONE.com<http://secure-web.cisco.com/1207WgAZMDcpTyLyU6tfKf0QUnLSpH9CY8uX_yFD3CQgcOhjXAultnrIYk05qAPwB6YhrwMymNus3dqebPLo4wxschb4L0sv_kRwtWPMLwusFjv4u6z4L-fgPCqIBOWBtPmRa5ONMRoaxfmNol5ckf0JhhxNqa63B_8KOZVSrGc5u-q45mKd8P47een8UULwwroRoz_KMGBT2ZO0rRvRwNg/http%3A%2F%2Fwww.SI-BONE.com>

From: Jayasri (Jai) Prabakaran

Sent: Friday, January 19, 2024 2:43 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <dcher@si-bone.com<mailto:dcher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,

I have reviewed and accept the changes proposed below to the 510(k) summary.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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www.SI-BONE.com<http://secure-web.cisco.com/1207WgAZMDcpTyLyU6tfKf0QUnLSpH9CY8uX_yFD3CQgcOhjXAultnrIYk05qAPwB6YhrwMymNus3dqebPLo4wxschb4L0sv_kRwtWPMLwusFjv4u6z4L-fgPCqIBOWBtPmRa5ONMRoaxfmNol5ckf0JhhxNqa63B_8KOZVSrGc5u-q45mKd8P47een8UULwwroRoz_KMGBT2ZO0rRvRwNg/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Friday, January 19, 2024 2:28 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Thursday, January 18, 2024 5:21 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510(k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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www.SI-BONE.com<http://secure-web.cisco.com/1VVayDOfVIJz7EfPrMYakKFmApdfO_Im9XdOvWAQKlzdDn-_kbldzpnsgEQEqvaoZC1w9H07_qIV9LR4WLDWV0e_xoRC4rBvBhttGS6OH3WJF6FAJc_HoAN94B3tRllQ-BKkyz2r0FXRMzexGboi7CO_Jqflw3uZfXDf8HpDwl7eljL7f-lk5jWvnRZpnfPhJAZpOB2u91hXRH2wlcccYGA/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 18, 2024 11:45 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Thursday, January 18, 2024 12:34 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

I am following up to see if you have any updates on K233508. Do you think we will be receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblS

np-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 11, 2024 1:39:34 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Monday, January 8, 2024 11:28 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hello Mr. Miller,

Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,

Jai Prabakaran, MBS (Regulatory & Clinical), RAC

Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050

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From: Sean Miller [SEAN.MILLER]
<sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Sent: Friday, December 29, 2023 7:15 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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U.S. FOOD & DRUG ADMINISTRATION

Si-Bone, Inc.
Jayasri Prabakaran
Associate Director, Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 95050

January 26, 2024

Re: K233508
Trade/Device Name: iFuse Bedrock Granite® Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, NKB, OLO
Dated: October 31, 2023
Received: October 31, 2023

Dear Jayasri Prabakaran:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eileen Cadel -S Digitally signed by Eileen Cadel -S Date: 2024.01.26 15:14:24 -05'00' for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

```
December 29, 2023</br></br>

<font face="arial">

<b>Substantive  Review  Notification - Proceed Interactively</b>

<br/><br/>

</font>


<p>FDA has completed a substantive review of your submission K233508 and has determined
that we will work with you to resolve outstanding deficiencies through an Interactive
Review process. Any outstanding deficiencies will be provided to you during the
Interactive Review process.</p>

<br><br><br><p>*** This is a system-generated email notification ***</p>
```

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233508

Device Name
iFuse Bedrock Granite® Implant System

Indications for Use *(Describe)*
The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
• To augment immobilization and stabilization of the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

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."

Thank you, Sean. Appreciate your quick response. We will review the IFU updates and get back to you.

Can you please let us know if this the only question or are we expecting more questions later today?

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 18, 2024 11:45 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: K233508@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 12:34 PM
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I am following up to see if you have any updates on K233508. Do you think we will be receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,
Jai Prabakaran
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www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 11, 2024 1:39:34 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Monday, January 8, 2024 11:28 AM
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Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hello Mr. Miller,
Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,
Jai Prabakaran, MBS (Regulatory & Clinical), RAC
Associate Director, Regulatory Affairs

SI-BONE logo_One color and

471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Sent: Friday, December 29, 2023 7:15 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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Hi Jai,

Unfortunately I do not have a definitive answer on that for you at this time. I have forwarded your question to our program staff, and I will relay their response to you once they have discussed it internally (likely sometime next week). Regardless, the final decision for this submission will be processed shortly.

Thank you for your patience,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 25, 2024 4:16 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: Daniel Cher <DCher@si-bone.com>; K233508@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,

(b)(4)

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 25, 2024 12:15 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Daniel Cher <DCher@si-bone.com>; K233508@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

(b)(4)

Please confirm by COB today (1/25/2024) that you acknowledge this email that (b)(4) does not apply to the current submission (K233508).

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Tuesday, January 23, 2024 5:11 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
Appreciate this update. Thank you.

Best regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Tuesday, January 23, 2024 2:07 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

We are currently finalizing our review. While I can't give an exact date on the decision, we do not believe it will be too much longer. If we need anything more from you I'll be sure to contact you,

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Tuesday, January 23, 2024 11:11 AM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
Hope you had a good weekend. Our team is curious to know if a decision will be made by this week. So please let me know if any other information is needed from our end.

Thanks again for your timely review!

Best regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Jayasri (Jai) Prabakaran
Sent: Friday, January 19, 2024 2:43 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov; Daniel Cher <dcher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
I have reviewed and accept the changes proposed below to the 510(k) summary.

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
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To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 5:21 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510 (k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs
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The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

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December 29, 2023

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIB
WO66 RM4422
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: December 21, 2023

Reviewer: Sean Miller

510(k)# K233508 Subject: Traditional

Applicant: Si-Bone, Inc.	**Device Trade Name:** iFuse Bedrock Granite Implant System (Multiple)
Contact Name: Jayasri Prabakaran	**Contact Title:** Associate Director, Regulatory Affairs
Correspondent Firm: Si-Bone, Inc.	**Phone:** (b)(6) **Email:** jayasri.prabakaran@si-bone.com
Received Date: October 31, 2023	**Due Date:** January 29, 2024
Pro Code(s): OUR, NKB, OLO **Class:** II **Reg #:** 888.3040	**Reg Name:** Smooth Or Threaded Metallic Bone Fixation Fastener

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K222774	OUR, NKB, OLO	iFuse Bedrock Granite® Implant System	SI-BONE, Inc.
K223494	NKB, KWP, KWQ, HBE, OLO	CD Horizon Spinal System	Medtronic
K223273	NKB, KWP, KWQ	ASTRA Spine System	SpineCraft, LLC

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(b)(5)

(b)(5)

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(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

Hi Jai,

No, this should be our only question.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 3:10 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Thank you, Sean. Appreciate your quick response. We will review the IFU updates and get back to you.

Can you please let us know if this the only question or are we expecting more questions later today?

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 18, 2024 11:45 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: K233508@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 12:34 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
I am following up to see if you have any updates on K233508. Do you think we will be receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,
Jai Prabakaran
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 11, 2024 1:39:34 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Monday, January 8, 2024 11:28 AM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hello Mr. Miller,
Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,
Jai Prabakaran, MBS (Regulatory & Clinical), RAC
Associate Director, Regulatory Affairs

SI-BONE logo_One color and

471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Sent: Friday, December 29, 2023 7:15 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K233508

Device Name
iFuse Bedrock Granite® Implant System

Indications for Use *(Describe)*
The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
• To augment immobilization and stabilization of the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

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.

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

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Hi Jai,

(b)(4)

Please confirm by COB today (1/25/2024) that you acknowledge this email that (b)(4) does not apply to the current submission (K233508).

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>

Sent: Tuesday, January 23, 2024 5:11 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov>

Cc: Daniel Cher <DCher@si-bone.com>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

Appreciate this update. Thank you.

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1jWeP7iOdiTzaL9AZyaq9h_HyUod_5GVR59T01yfxcJWpb7adv86YUMSOmq7v7vU6-KW4rPG35pxKkzuJReOtqEpG7Wa1e8V1VPUiXO_DlM7vpw-MlUQbOxB8EOOEm61g4RUwu0rOaiiKhBudjk_MSR0SxELLXx9ckPF60c3TTfZBUhlq-ms_ZduANgMJ6JF7luv0DxfQbj3MQvC1aSQyLA/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Tuesday, January 23, 2024 2:07 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

We are currently finalizing our review. While I can't give an exact date on the decision, we do not believe it will be too much longer. If we need anything more from you I'll be sure to contact you,

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Tuesday, January 23, 2024 11:11 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

Hope you had a good weekend. Our team is curious to know if a decision will be made by this week. So please let me know if any other information is needed from our end.

Thanks again for your timely review!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1207WgAZMDcpTyLyU6tfKf0QUnLSpH9CY8uX_yFD3CQgcOhjXAultnrIYk05qAPwB6YhrwMymNus3dqebPLo4wxschb4L0sv_kRwtWPMLwusFjv4u6z4L-fgPCqIBOWBtPmRa5ONMRoaxfmNol5ckf0JhhxNqa63B_8KOZVSrGc5u-q45mKd8P47een8UULwwroRoz_KMGBT2ZO0rRvRwNg/http%3A%2F%2Fwww.SI-BONE.com>

From: Jayasri (Jai) Prabakaran

Sent: Friday, January 19, 2024 2:43 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <dcher@si-bone.com<mailto:dcher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,

I have reviewed and accept the changes proposed below to the 510(k) summary.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1207WgAZMDcpTyLyU6tfKf0QUnLSpH9CY8uX_yFD3CQgcOhjXAultnrIYk05qAPwB6YhrwMymNus3dqebPLo4wxschb4L0sv_kRwtWPMLwusFjv4u6z4L-fgPCqIBOWBtPmRa5ONMRoaxfmNol5ckf0JhhxNqa63B_8KOZVSrGc5u-q45mKd8P47een8UULwwroRoz_KMGBT2ZO0rRvRwNg/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Friday, January 19, 2024 2:28 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Thursday, January 18, 2024 5:21 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510(k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1VVayDOfVIJz7EfPrMYakKFmApdfO_Im9XdOvWAQKlzdDn-_kbldzpnsgEQEqvaoZC1w9H07_qIV9LR4WLDWV0e_xoRC4rBvBhttGS6OH3WJF6FAJc_HoAN94B3tRllQ-BKkyz2r0FXRMzexGboi7CO_Jqflw3uZfXDf8HpDwl7eljL7f-lk5jWvnRZpnfPhJAZpOB2u91hXRH2wlcccYGA/http%3A%2F%2Fwww.SI-BONE.com>

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Sent: Thursday, January 18, 2024 11:45 AM

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Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

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To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

I am following up to see if you have any updates on K233508. Do you think we will be receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 11, 2024 1:39:34 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,

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Sent: Monday, January 8, 2024 11:28 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hello Mr. Miller,

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If you need any additional information, please let me know.

Thanks and regards,

Jai Prabakaran, MBS (Regulatory & Clinical), RAC

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Sent: Friday, December 29, 2023 7:15 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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510(k) SUMMARY

iFuse Bedrock Granite® Implant System

I. 510(k) SUBMITTER

SI-BONE, Inc.
471 El Camino Real, Suite 101,
Santa Clara, CA 95050
Phone: 408-207-0700
Fax: 408-557-8312

Contact Person: Jayasri Prabakaran, Associate Director, Regulatory Affairs

FDA Establishment Registration No.: 3007700286

Date Prepared: January 18, 2024

II. DEVICE

Trade Name of Device	iFuse Bedrock Granite® Implant System
Classification Name	Sacroiliac Joint Fixation
Classification	II
Regulation Number	21 CFR 888.3040; Smooth or threaded metallic bone fastener 21 CFR 888.3070, Thoracolumbosacral pedicle screw system 21 CFR 882.4560, Stereotaxic instrument
Product Code	OUR, NKB, OLO

III. PREDICATE DEVICES

Primary Predicate:

Predicate Device	Manufacturer	510(k)#	Clearance Date
iFuse Bedrock Granite Implant System	SI-BONE, Inc.	K222774	December 22, 2022

Additional Predicates:

Predicate Device	Manufacturer	510(k)#	Clearance Date
CD Horizon Spinal System	Medtronic Sofamor Danek	K223494	January 23, 2023
SpineCraft, LLC	SpineCraft, LLC	K223273	December 22, 2022

IV. DEVICE DESCRIPTION

The iFuse Bedrock Granite® Implant System consists of implants of various lengths and diameters, and associated instruments sets. Instrument sets are provided for both open and minimally invasive approaches. The titanium (Ti-6Al-4V ELI) implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the iliac trajectories. Additionally, iFuse Bedrock Granite can be placed into the S1 pedicle. The device is designed for connection to commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm titanium alloy or cobalt chrome alloy spinal fixation rods.

V. INDICATIONS FOR USE

The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
• To augment immobilization and stabilization of the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse

Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

VI. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The subject device is substantially equivalent to its predicate in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. The differences in the indication for use statement from the previously cleared legally marketed predicate are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, iFuse Bedrock Granite Implant System is substantially equivalent to its predicate device.

VII. PERFORMANCE DATA

SI-BONE performed the following performance tests:

- Static and Dynamic Cantilever Testing per ASTM F2193
- Post-Fatigue Sleeve Dissociation Testing
- Static Torsion Testing per ASTM 543
- Static Axial Pull out Testing per ASTM 543
- Characterizing the Porous Surface Bedrock Granite Test (Static Shear, Shear Fatigue, Static Tensile, Abrasion Properties)
- Construct Testing per ASTM F1717 (Static and Dynamic Compression Bending, Static Torsion)

The test results demonstrate that the device is substantially equivalent to the predicate device.

VIII. CONCLUSION

The modified iFuse Bedrock Granite implant (reduced diameter and length) is substantially equivalent to its predicate in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. Testing has shown substantially equivalent benchtop performance. The differences in the indication for use statement from previous cleared legally marketed predicates are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Test results demonstrate that the device is substantially equivalent to the legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

Hi Jai,

(b)(4)

Please confirm by COB today (1/25/2024) that you acknowledge this email that (b)(4) does not apply to the current submission (K233508).

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Tuesday, January 23, 2024 5:11 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
Appreciate this update. Thank you.

Best regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

SI-BONE logo_One color and

471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Tuesday, January 23, 2024 2:07 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

We are currently finalizing our review. While I can't give an exact date on the decision, we do not believe it will be too much longer. If we need anything more from you I'll be sure to contact you,

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Tuesday, January 23, 2024 11:11 AM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
Hope you had a good weekend. Our team is curious to know if a decision will be made by this week. So please let me know if any other information is needed from our end.

Thanks again for your timely review!

Best regards,
Jai Prabakaran

Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Jayasri (Jai) Prabakaran
Sent: Friday, January 19, 2024 2:43 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov; Daniel Cher <dcher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
I have reviewed and accept the changes proposed below to the 510(k) summary.

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

SI-BONE logo_One color and

471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Friday, January 19, 2024 2:28 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 5:21 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510 (k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

SI-BONE logo_One color and

471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com

www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 18, 2024 11:45 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: K233508@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 12:34 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
I am following up to see if you have any updates on K233508. Do you think we will be receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,
Jai Prabakaran
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 11, 2024 1:39:34 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Monday, January 8, 2024 11:28 AM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hello Mr. Miller,
Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,
Jai Prabakaran, MBS (Regulatory & Clinical), RAC
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Sent: Friday, December 29, 2023 7:15 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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Thank you,

Sean

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To: Miller, Sean <Sean.Miller@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Thanks and have a good day!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 11, 2024 1:39:34 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

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Sent: Monday, January 8, 2024 11:28 AM

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If you need any additional information, please let me know.

Thanks and regards,

Jai Prabakaran, MBS (Regulatory & Clinical), RAC

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

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Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Sean Miller [SEAN.MILLER]
<sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Sent: Friday, December 29, 2023 7:15 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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January 26, 2024</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Sean Miller.

 *** This is a system-generated email notification ***

November 13, 2023</br></br>

Review Assignment Notification

I am the lead reviewer assigned to your submission K233508. Your file is being reviewed in Office of Health Technology 6, Division of Health Technology 6 B. The first line supervisor is the Assistant Director of Extracolumnar Spinal Devices.

I will contact you should any additional information be required during the course of the review of your submission. You may contact me at any point during the review if you have questions or concerns. FDA aims to apply the least burdensome principles when requesting additional information.

You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

 *** This is a system-generated email notification ***

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIB
WO66 RM4422
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Date: January 22, 2024

Reviewer: Sean Miller

510(k)# K233508 Subject: Traditional

Applicant: Si-Bone, Inc.	**Device Trade Name:** iFuse Bedrock Granite® Implant System
Contact Name: Jayasri Prabakaran	**Contact Title:** Associate Director, Regulatory Affairs
Correspondent Firm: Si-Bone, Inc.	**Phone:** (b)(6) **Email:** jayasri.prabakaran@si-bone.com
Received Date: October 31, 2023	**Due Date:** January 29, 2024
Pro Code(s): OUR, NKB, OLO **Class:** II **Reg #:** 888.3040	**Reg Name:** Smooth Or Threaded Metallic Bone Fixation Fastener

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K222774	OUR, NKB, OLO	iFuse Bedrock Granite® Implant System	SI-BONE, Inc.
K223494	NKB, KWP, KWQ, HBE, OLO	CD Horizon Spinal System	Medtronic
K223273	NKB, KWP, KWQ	ASTRA Spine System	SpineCraft, LLC

Recommendation

I recommend that the iFuse Bedrock Granite® Implant System is/are Substantially Equivalent (SESE)

(b)(5)

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U.S. FOOD & DRUG ADMINISTRATION

Si-Bone, Inc.
Jayasri Prabakaran
Associate Director, Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 95050

January 26, 2024

Re: K233508
Trade/Device Name: iFuse Bedrock Granite® Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, NKB, OLO
Dated: October 31, 2023
Received: October 31, 2023

Dear Jayasri Prabakaran:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Eileen Cadel -S Digitally signed by Eileen Cadel -S Date: 2024.01.26 15:14:24 -05'00' for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K233508

Device Name
iFuse Bedrock Granite® Implant System

Indications for Use *(Describe)*
The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
• To augment immobilization and stabilization of the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

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.

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Department of Health and Human Services
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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."

510(k) SUMMARY

iFuse Bedrock Granite® Implant System

I. 510(k) SUBMITTER

SI-BONE, Inc.
471 El Camino Real, Suite 101,
Santa Clara, CA 95050
Phone: 408-207-0700
Fax: 408-557-8312

Contact Person: Jayasri Prabakaran, Associate Director, Regulatory Affairs

FDA Establishment Registration No.: 3007700286

Date Prepared: January 18, 2024

II. DEVICE

Trade Name of Device	iFuse Bedrock Granite® Implant System
Classification Name	Sacroiliac Joint Fixation
Classification	II
Regulation Number	21 CFR 888.3040; Smooth or threaded metallic bone fastener 21 CFR 888.3070, Thoracolumbosacral pedicle screw system 21 CFR 882.4560, Stereotaxic instrument
Product Code	OUR, NKB, OLO

III. PREDICATE DEVICES

Primary Predicate:

Predicate Device	Manufacturer	510(k)#	Clearance Date
iFuse Bedrock Granite Implant System	SI-BONE, Inc.	K222774	December 22, 2022

Additional Predicates:

Predicate Device	Manufacturer	510(k)#	Clearance Date
CD Horizon Spinal System	Medtronic Sofamor Danek	K223494	January 23, 2023
SpineCraft, LLC	SpineCraft, LLC	K223273	December 22, 2022

IV. DEVICE DESCRIPTION

The iFuse Bedrock Granite® Implant System consists of implants of various lengths and diameters, and associated instruments sets. Instrument sets are provided for both open and minimally invasive approaches. The titanium (Ti-6Al-4V ELI) implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the iliac trajectories. Additionally, iFuse Bedrock Granite can be placed into the S1 pedicle. The device is designed for connection to commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm titanium alloy or cobalt chrome alloy spinal fixation rods.

V. INDICATIONS FOR USE

The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
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The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse

Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

VI. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The subject device is substantially equivalent to its predicate in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. The differences in the indication for use statement from the previously cleared legally marketed predicate are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, iFuse Bedrock Granite Implant System is substantially equivalent to its predicate device.

VII. PERFORMANCE DATA

SI-BONE performed the following performance tests:

- Static and Dynamic Cantilever Testing per ASTM F2193
- Post-Fatigue Sleeve Dissociation Testing
- Static Torsion Testing per ASTM 543
- Static Axial Pull out Testing per ASTM 543
- Characterizing the Porous Surface Bedrock Granite Test (Static Shear, Shear Fatigue, Static Tensile, Abrasion Properties)
- Construct Testing per ASTM F1717 (Static and Dynamic Compression Bending, Static Torsion)

The test results demonstrate that the device is substantially equivalent to the predicate device.

VIII. CONCLUSION

The modified iFuse Bedrock Granite implant (reduced diameter and length) is substantially equivalent to its predicate in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. Testing has shown substantially equivalent benchtop performance. The differences in the indication for use statement from previous cleared legally marketed predicates are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Test results demonstrate that the device is substantially equivalent to the legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 5:21 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510 (k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 18, 2024 11:45 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
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Hi Jai,

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The main points of the revisions are as follows:

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Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

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Thanks and have a good day!

Best regards,
Jai Prabakaran
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From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 11, 2024 1:39:34 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
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Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,
Sean

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Sent: Monday, January 8, 2024 11:28 AM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hello Mr. Miller,
Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,
Jai Prabakaran, MBS (Regulatory & Clinical), RAC
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Sent: Friday, December 29, 2023 7:15 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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Hi Sean,

I have reviewed and accept the changes proposed below to the 510(k) summary.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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From: Miller, Sean <Sean.Miller@fda.hhs.gov>

Sent: Friday, January 19, 2024 2:28 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>

Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Thursday, January 18, 2024 5:21 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

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http://secure-web.cisco.com/14YWJ6TTzrOkCHNGN3sJNLKVgDUzKahiEklatu1Y1LWFWwjvIamju9uUMxjGaZUVaygiNRkVU5qf7mpmsLNxpT6e_FJOzyyvJTuIgv0abxEdc9pIU6rd4k1f_lWfsOZ0piuQBgSfMhwqxuvB_BuTm3L79jmrRxpAXv0zqahAG9mvQgOn4HwakK9RxRpGjpq2-/http%3A%2F%2Fwww.SI-BONE.com<http://secure-web.cisco.com/1VVayDOfVIJz7EfPrMYakKFmApdfO_Im9XdOvWAQKlzdDn-_kbldzpnsgEQEqvaoZC1w9H07_qIV9LR4WLDWV0e_xoRC4rBvBhttGS6OH3WJF6FAJc_HoAN94B3tRllQ-BKkyz2r0FXRMzexGboi7CO_Jqflw3uZfXDf8HpDwl7eljL7f-lk5jWvnRZpnfPhJAZpOB2u91hXRH2wlcccYGA/http%3A%2F%2Fwww.SI-BONE.com>

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471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

http://secure-web.cisco.com/14YWJ6TTzrOkCHNGN3sJNLKVgDUzKahiEklatu1Y1LWFWwjvIamju9uUMxjGaZUVaygiNRkVU5qf7mpmsLNxpT6e_FJOzyyvJTuIgv0abxEdc9pIU6rd4k1f_lWfsOZ0piuQBgSfMhwqxuvB_BuTm3L79jmrRxpAXv0zqahAG9mvQgOn4HwakK9RxRpGjpq2-/http%3A%2F%2Fwww.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Sent: Friday, December 29, 2023 7:15 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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SI-BONE

K233508

October 31, 2023

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

RE: Traditional 510(k) Premarket Notification
SI-BONE, Inc. iFuse Bedrock Granite

Attention: Mr. Colin O'Neill, M.S.
DHT6B Extracolumnar Spinal Devices
Division of Health Technology 6 B (Spinal Devices)
Office of Health Technology 6 (OHT 6: Orthopedic Devices)

Dear Mr. O'Neill and 510(k) Review Team,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and 21 C.F.R. § 807, SI-BONE, Inc. ("SI-BONE") is submitting this Traditional 510(k) premarket notification for the iFuse Bedrock Granite Implant System, consisting of the iFuse Bedrock Granite Implant and associated instruments. This submission has been prepared in accordance with the recommendations made by the Agency in the FDA Guidance: *Format for Traditional and Abbreviated 510(k)s* issued on September 13, 2019, and is in accordance with the *Electronic Submission Template for Medical Device 510(k) Submissions* issued on October 2, 2023.

The subject device, iFuse Bedrock Granite Implant and associated instruments, (b)(4) (b)(4) (b)(4) Following that, the device was cleared as part of K222774 on December 22, 2022, to expand the indications for the subject device to include compatibility with 5.5- and 6.0 mm titanium alloy and cobalt chrome alloys Pedicle Screw Systems rods. The intended use of the subject device is sacroiliac (SI) joint fusion and pelvic fixation during thoracolumbar spine fusion surgeries.

The purpose of the current submission is to include the following changes to the iFuse bedrock Granite Implant:

(b)(4)

(b)(4)

The subject device is slightly smaller in diameter (Ø 9.5 mm vs. Ø10.5 mm – Ø13.5 mm for the primary predicate) and slightly shorter (smallest length 40 mm vs. 45-120 mm for the primary predicate). The smaller dimensions introduce a new lower limit for diameter and length. The new size offering will allow the implant to be placed in smaller anatomical corridors compared to the previously cleared primary predicate device. The indications for use of the iFuse Bedrock Granite Implant System are also proposed to be expanded to include pediatric population similar to the secondary predicate devices. (b)(4)

(b)(4)

This 510(k) describes the performance testing conducted to support the reduced size offering of the implant. The testing did not raise different questions of safety and effectiveness compared to the predicate device. Therefore, test results support adequate expected performance of the line extension as well as substantial equivalence between the subject device and its cleared predicate.

We request that the Food and Drug Administration hold confidential the information of our intent to seek 510(k) clearance for the subject device and the information provided in this submission, pursuant to 21 CFR 807.95.

We thank the Agency for its review of this application. I am available for any questions using the below contact information.

Sincerely,

DocuSigned by:
(b)(6)

Jayasri Prabakaran
Associate Director of Regulatory Affairs
SI-BONE, Inc.
471 El Camino Real, Suite 101
Santa Clara, CA 95050
Mobile: (b)(6)
Email: Jayasri.Prabakaran@si-bone.com

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>

Sent: Thursday, January 18, 2024 5:21 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov>

Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sean,

SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510(k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1VVayDOfVIJz7EfPrMYakKFmApdfO_Im9XdOvWAQK1zdDn-_kbldzpnsgEQEqvaoZC1w9H07_qIV9LR4WLDWV0e_xoRC4rBvBhttGS6OH3WJF6FAJc_HoAN94B3tRl1Q-BKkyz2r0FXRMzexGboi7CO_Jqflw3uZfXDf8HpDwl7eljL7f-lk5jWvnRZpnfPhJAZpOB2u91hXRH2wlcccYGA/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 18, 2024 11:45 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Thursday, January 18, 2024 12:34 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,

I am following up to see if you have any updates on K233508. Do you think we will be

receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

_____

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 11, 2024 1:39:34 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Monday, January 8, 2024 11:28 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hello Mr. Miller,

Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,

Jai Prabakaran, MBS (Regulatory & Clinical), RAC

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

www.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Sent: Friday, December 29, 2023 7:15 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Subject: K233508 review will proceed via interactive review

December 29, 2023

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electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 4.3 (2023-10-02)*

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g. guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: For technical issues or bug reports please email eSubPilot@fda.hhs.gov.
For regulatory process or content questions please email:
USFDA: DICE@fda.hhs.gov
Health Canada: meddevices-instrumentsmed@hc-sc.gc.ca

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type, attachment name, or size restriction?
A: Unacceptable attachment types and names are automatically prevented. If an attachment is great than 1 GB,

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g. 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g. 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

4.3 (2023-10-02): Standard recognition number can now be used to autopopulate standard information. Texts updated

Application/Submission Type

Application Jurisdiction	(●) US FDA ( ) Health Canada	?

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510 (k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	(●) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA	?

Show Application Introduction

Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	(●) Traditional ( ) Abbreviated ( ) Special

Show Application Type Introduction

Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	(●) New Application/Submission ( ) Additional Information	?

Cover Letter / Letters of Reference

Add Attachment | Attach your Cover Letter

Open Attachment | Attachment_1_Cover_Letter.pdf | Delete Attachment

Add Attachment | Attach any Letters of Reference

Applicant Information

Contact

Title	Ms.
Last Name	Prabakaran
First Name	Jayasri
Email	Jayasri.Prabakaran@si-bone.com
Phone Number	(b)(6)
Occupation Title	Associate Director, Regulatory Affairs

Company

Company Name	SI-Bone Inc.
Address - Line 1	471 El Camino Real, Suite 101
Address - Line 2	
City	Santa Clara
State	CA
Zip	95050
Country/Region	United States

Add Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)? No

Standards

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. A recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators request standards information be attached.

ISO	14971 Third Edition 2019-12	5-125	Delete Standard

Medical devices - Application of risk management to medical devices

Are you using this standard for general use, or are you declaring conformity to it? General Use

Add Standard

ASTM	F136-13	8-377	Delete Standard

Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgica

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Standard

ASTM	F1854-15	8-400	Delete Standard
Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants			

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Standard

ASTM	F1044-05 (Reapproved 2017)e1	8-112	Delete Standard
Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings			

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Standard

ASTM	F1147-05 (Reapproved 2017)e1	8-113	Delete Standard
Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings			

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Standard

ASTM	F1978-18	8-467	Delete Standard
Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber A			

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Standard

ASTM	F1160-14 (Reapproved 2017)e1	8-380	Delete Standard
Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Con			

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Standard

ASTM	F3001-14	8-439	Delete Standard
Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) w			

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Standard

ASTM	F2193-20	11-375	Delete Standard

Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal Syst

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F543-17	11-327	Delete Standard

Standard Specification and Test Methods for Metallic Medical Bone Screws

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F1717-21	11-388	Delete Standard

Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F1798-13	11-276	Delete Standard

Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassembli

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F3127-16	8-442	Delete Standard

Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	D4332-14	5-99	Delete Standard

Standard Practice for Conditioning Containers Packages or Packaging Components for Testing

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	D3078-02 (Reapproved 2021)e1	14-257	Delete Standard

Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?
Add Standard			
ASTM	F1980-16	14-497	Delete Standard
Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?
Add Standard			
ISO	15223-1 Fourth edition 2021-07	5-134	Delete Standard
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requir			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?
Add Standard			
ISO	17664-1 First edition 2021-07	14-578	Delete Standard
Processing of health care products - Information to be provided by the medical device manufacturer for the proce			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?
Add Standard			

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

iFuse Bedrock Granite Implant System	Multiple	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	No
Are there any direct or indirect tissue contacting components?	Yes
• Is the device or a component an implant?	Yes
Does the device use software/firmware?	No
Is the device or a component packaged as sterile?	Yes
The device/system uses or is... (choose all that apply)	☒ a single use device(s), non-sterile or packaged as sterile ☐ a single use device(s), terminal/end user sterilized ☐ a reusable single patient use device(s) ☐ a reusable multi-patient use device(s)
The environment of use of the device/system includes... (choose all that apply)	☒ Professional Healthcare Facility ☐ Home Environment ☐ Magnetic Resonance (MR) Environment ☐ Transport (Ambulatory) Environment ☐ Other Environment
Is the device a combination product or does a Request For Designation (RFD) / pre-RFD exist for the product?	No (most common)
Is the device electrical (battery or wall powered)?	No, the device is not electrical
Please check the attributes that are applicable to your device. If none apply, keep all unchecked.	☐ Medical Counter Measures Device ☐ Nanotechnology ☐ Reprocessed Single Use Device ☐ Animal-Derived Material(s) ☐ Predetermined Change Control Plan

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The iFuse Bedrock Granite Implant System consists of implants of various lengths and diameters, and associated instrument sets for both open and minimally invasive (MIS) approaches. The titanium (Ti-6Al-4V ELI) implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the Iliac trajectories. It is designed for connection to commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm titanium alloy or cobalt chrome alloys spinal fixation rods.

The subject device is slightly smaller in diameter (9.5 mm) and is provided in lengths slightly shorter (40 mm). The surface of the sleeve is also slightly different (see below). Otherwise, the subject device is identical to previously cleared iFuse Bedrock Granite implants.

Based on feedback from surgeon customers, this 510k includes optional placement of the subject device in the S1 trajectory. This trajectory does not imply any change to the intended use nor use steps of the subject device (i.e., placement within bone and attachment to posterior spinal rods). This trajectory is commonly used by surgeons performing thoracolumbar fusions.

Note that there are no new or unique instruments required for implantation of the subject 9.5 mm iFuse Bedrock Granite Implant. The same Open (P/N 400309) and MIS (P/N 400310) Instrument Sets cleared under K220195 are also utilized for the subject 9.5 mm Granite Implant.

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	Attachment 3A_Device Description.pdf	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	Attachment 3B_Model numbers_Engg Drawings.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	Attachment 3C_Device Packaging Description.pdf	Delete Attachment

System/Kit Components and Accessories

Is the device intended to be marketed with multiple system/kit components or accessories? No ?

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

N/A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

(b)(4)

Indications for Use *(Describe)*

(b)(4)

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."

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450). ?

Medical Specialty	Orthopedic
Regulation	888.3040 - Smooth or threaded metallic bone fixation fastener
Product Code	OUR (Class 2) - Sacroiliac Joint Fixation
Associated Product Code(s)	NKB, OLO ?

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	No
Predicate Submission Number (e.g., K210001)	K222774
Predicate Device Trade Name	iFuse Bedrock Granite Implant System
Predicate Device Primary Product Code	
Medical Specialty	Orthopedic
Regulation	888.3040 - Smooth or threaded metallic bone fixation fastener
Product Code	OUR, NKB, OLO

Add Predicate/Reference Device | Delete Predicate/Reference Device

Predicate/Reference Device

Is this a Preamendments or Exempt device without a submission number?	No
Predicate/Reference Submission Number (e.g., K210001)	K223494
Predicate/Reference Device Trade Name	CD Horizon Spinal System
Predicate/Reference Device Primary Product Code	
Medical Specialty	Orthopedic
Regulation	888.3070 - Thoracolumbosacral pedicle screw system
Product Code	NKB, KWP, KWQ

Add Predicate/Reference Device | Delete Predicate/Reference Device

Predicate/Reference Device

Is this a Preamendments or Exempt device without a submission number?	No
Predicate/Reference Submission Number (e.g., K210001)	K223273
Predicate/Reference Device Trade Name	ASTRA Spine System
Predicate/Reference Device Primary Product Code	
Medical Specialty	Orthopedic
Regulation	888.3070 - Thoracolumbosacral pedicle screw system
Product Code	NKB, KWP, KWQ

Add Predicate/Reference Device | Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Both the subject device and the primary predicate device have the same intended use for sacroiliac joint fusion and augmenting immobilization and stabilization. The proposed indications for use statement of the subject device is different from the primary predicate device; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicates.

The proposed indications for use statement for the iFuse Bedrock Granite Implant System was amended with language describing use of the subject device in the pediatric population, similar to the secondary predicate devices.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The subject device is the primary predicate. There are no changes in the subject device compared to the cleared primary predicate except for the new size offerings. The current iFuse Bedrock Granite Implant is manufactured in diameters between Ø10.5 mm – Ø13.5 mm and in lengths to accommodate the threaded screw post length range of 45 mm -120 mm. The proposed iFuse Bedrock Granite Implant will be manufactured with a diameter of Ø9.5 mm and available in lengths of 40 mm to 120 mm (in 5mm increments), thus introducing a new lower limit for diameter and length. The slightly smaller size for the subject device allows it to be placed into smaller anatomical corridors compared to the previously cleared primary predicate device.

The subject device is very similar to the predicates as follows:
• Design: the subject device and the primary predicate are threaded implants (screws) with a porous fusion sleeve; the secondary predicates are threaded implants (screws).
• Diameter: the subject device includes a smaller diameter of 9.5 mm when compared to the previously cleared primary predicate (Ø10.5 mm – Ø13.5 mm) but lies within the range of diameters offered by the secondary predicates.
• Implant lengths: the subject device includes a smaller length option of 40 mm as a line extension to the range offered by the previously cleared primary predicate (45-120 mm). The implant length lies within the range offered by the secondary predicates.
• Surface design: the subject device's surface has a porous and fenestrated surface design similar to the primary predicate.
• Manufacturing: the subject device and the primary predicate have an implant post that is traditionally machined and a sleeve that is additively manufactured and traditionally machined.

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s). If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.	?
Open Attachment	Attachment 5_Substantial Equivalence Comparison.pdf	Delete Attachment

Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).	iFuse Bedrock Granite Implant System - Instructions for Use (IFU) (b)(4) (provided as Attachment 6B).
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?	Not Evaluated
If the device(s) contains a static/permanent magnet, please specifically cite the attachment and page number where labeling includes a statement and/or contraindication regarding the risk of magnet use within 6 inches of other magnetically susceptible medical devices. Type "N/A" if not applicable.	N/A

Package Labeling

Add Attachment — Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.

Open Attachment — Attachment 6_Labeling overview and Attachment 6A Product — Delete Attachment

Package Insert / Instructions for Use

Add Attachment — Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.

Open Attachment — Attachment 6B IFU REDLINES_CLEAN.pdf — Delete Attachment

Other Labeling

Add Attachment — Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

Healthcare Professional Labeling

Open Attachment — Attachment 6C_STM REDLINES.pdf — Delete Attachment

Healthcare Professional Labeling

Open Attachment — Attachment 6C_STM Clean.pdf — Delete Attachment

Healthcare Professional Labeling

Open Attachment — Attachment 6D_ Hospital Cleaning and Sterilization Instructions.pdf — Delete Attachment

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	iFuse Bedrock Granite Implant System - Instructions for Use (IFU)
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	iFuse Bedrock Granite Implant System - Instructions for Use (IFU) 501467
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	iFuse Bedrock Granite Implant System - Instructions for Use (IFU) 501467 Page 4 (provided as

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Labeling. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

N/A

Based on the answers provided in the Device Description section, sterility information, but no reprocessing information, is needed.

Sterility

How many sterilization methods are there (maximum of 4)?	1

Sterilization Method 1

Identify the device(s) / accessory(ies) / component(s) that is sterilized.

iFuse Bedrock Granite Implant

What is the Sterilization Method?	Radiation (Est A)
What is the dose?	(b)(4)
What standard(s) were used for validation?	

• SS EN ISO 11137-1:2015 - Sterilization of Health Care Products: Radiation Sterilization - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
• SS EN ISO 11137-2:2015 - Sterilization of Health Care Products: Radiation Sterilization - Part 2: Establishing the Sterilization Dose – Method VD-Max 25

What validation method was used for the sterilization cycle?	VDmax25 (b)(4)
What is the Sterility Assurance Level (SAL)?	10^-6
If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?	Not labeled nor required to be "Non-Pyrogenic"

Please provide a description of the packaging, the materials used, and a description of the package test methods.

(b)(4)

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Reprocessing or Sterility. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

N/A

Shelf-Life

Does your device have a shelf-life?	Yes	?
What is the proposed shelf-life?	5	Years

Provide a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, provide a rationale for why testing to establish shelf-life is not applicable.

a. Proposed Shelf-Life/ Expiration Date

(b)(4)

b. Packaging Validation to Maintain Sterile Barrier

(b)(4)

c. Device Performance Maintained Throughout the Entirety of Shelf-Life

(b)(4)

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment

Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.

?

Open Attachment Attachment 7_Reprocessing_Sterility.pdf Delete Attachment

Cleaning and Disinfection Validation

Open Attachment Attachment 7A - (b)(4) Cleaning Process for the iFuse Bedrock Delete Attachment

Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Tissue Contacting Products/Components/Materials

How many tissue contacting products/components/materials are there? *(See Help Text if multiple materials share the same justification for no testing.)*	1

Tissue Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

iFuse Bedrock Granite Implant (consisting of threaded screw post, fusion sleeve, tulip) and set screw

Please state the exact name and any identifiable information for the particular material used.

iFuse Bedrock Granite Implant: Ti-6Al-4V ELI per ASTM F136 and ASTM F3001
Set Screw: Titanium Ti-6Al-4V ELI per ISO 5823-3/ ASTM F136

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	(b)(4)

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Additional Biocompatibility testing is not needed since the implant materials and manufacturing/processing are identical to the predicate.

Are the listed components in contact with intact skin only AND are all the component materials included in Attachment G, Section B of the FDA Biocompatibility Guidance?	No
Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Implant Device: Tissue/Bone
Duration of Contact	> 30 days (i.e., permanent)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** If tests are conducted under the Accreditation Scheme for Conformity Assessment (ASCA), select the ASCA option and attach ASCA summary test reports. For instances where the complete test report should be provided in addition to the ASCA Summary Test Report, please refer to the ASCA Guidance for more information.

Cytotoxicity | Sensitization | Irritation | Acute Systemic & Pyrogenicity | Subacute/Subchronic
Genotoxicity | Implantation | Chronic | Carcinogenicity

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	(b)(4)
Identify the test article used in testing.	iFuse Bedrock Granite Implant and set screws

Extraction Conditions

Test Article Extraction Ratio	(b)(4)
Extraction Vehicle(s)	(b)(4)
Extraction Conditions	(b)(4)
Was the test extract diluted, filtered, or was the pH adjusted?	(b)(4)
Study Controls	(b)(4)
Extract/Test Article is clear (i.e., not cloudy/turbid, no particulates, no color change, no swelling/degradation of the test article)?	(b)(4)
Extract Storage Conditions	(b)(4)

Methods

Test System	(b)(4)
Assessment Times After Treatment	(b)(4)
Was the following scale used for test extract, reagent control, negative control and positive control? 0: discrete intracytoplasmic granules & no lysis 1: occasional lysed cells (0-20% cells rounded, loose) 2: no extensive cell lysis (20-50% cells rounded) 3: 50-70% lysis (50-70% cells rounded) 4: nearly complete destruction of cell layer (>70% lysis)	(b)(4)
Were there deviations?	(b)(4)

Results

Were there any cell abnormalities?	(b)(4)
Were cytotoxicity scores in the controls as expected (e.g., reagent and/or negative are noncytotoxic, positive is cytotoxic)?	(b)(4)

Conclusion

Cytotoxic Potential	(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

Close Tab

Sensitization Testing

What type of sensitization testing was conducted? (b)(4) ?

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted? (b)(4) ?

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Close Tab

Acute Systemic Toxicity Testing & Material Mediated Pyrogenicity Testing

Acute Systemic Toxicity Testing

Was Acute Systemic Toxicity testing conducted? (b)(4) ?

Material Mediated Pyrogenicity Testing

Was Material Mediated Pyrogenicity testing conducted? (b)(4) ?

Specific questions for these tests do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Acute Systemic Toxicity and and Material Mediated Pyrogenicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11 for Acute Systemic Toxicity and per ISO 10993-11 and USP <151> for Material Mediated Pyrogenicity. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Subacute/Subchronic Toxicity Testing

Was Subacute/Subchronic Toxicity testing conducted? (b)(4)

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Subacute/Subchronic Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Genotoxicity Testing

Was Genotoxicity Toxicity testing conducted? (b)(4)

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Genotoxicity Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-3 and ISO/TR 10993-33. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Implantation Testing

Was Implantation Toxicity testing conducted? (b)(4)

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Implantation Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-6. You may also like to consult ASTM F981-04, F1408-97, F1983-99, and F763-05 for more information, as well as the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Chronic Toxicity Testing

Was Chronic Toxicity testing conducted? (b)(4)

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Chronic Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Carcinogenicity Assessment

Was Carcinogenicity assessment conducted? (b)(4)

Specific questions for this endpoint do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Carcinogenicity be assessed. If in rare cases testing is needed, please contact FDA to discuss your proposed methods prior to initiation of the studies to ensure that the studies will be adequately designed to address FDA's concerns. Use of the Q-submission process may be helpful. Please provide the carcinogenicity assessment, or if applicable, the carcinogenicity test report in an attachment in the Biocompatibility Reports and Documentation section below. Please also see the Biocompatibility Guidance.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.	
Open Attachment	Attachment 8_Biocompatibility.pdf	Delete Attachment

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, no software, cybersecurity, or interoperability information is needed.

EMC, Wireless, Electrical, Mechanical, and Thermal Safety

Based on the answers provided in the Device Description section, no EMC or wireless technology information is needed. You should still address Mechanical and Thermal safety testing in the textbox below.

Electrical, Mechanical, and Thermal (EMT) Safety Summary

Please summarize the Electrical, Mechanical and Thermal Safety Testing of your device, or summarize why testing was not needed. Please ensure any standards used here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence). Attach any supporting documentation for each standard used in your testing to the EMC, Wireless, & EMT Documentation section below.

N/A

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.

Performance Testing

Was Bench Testing used in order to support this submission?	Yes
Was Animal Testing used in order to support this submission?	No
Was Clinical Testing used in order to support this submission?	No

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92 (b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here. ?

SI-BONE performed the following performance tests:
- Static and Dynamic Cantilever Testing per ASTM F2193
- Static Torsion Testing per ASTM 543
- Static Axial Pull out Testing per ASTM 543
- Characterizing the Porous Surface Bedrock Granite Test (Static Shear, Static Fatigue, Static Tensile, Abrasion Properties)
- Construct Testing per ASTM F1717 (Static Axial Compression)

The test results demonstrate that the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

The Performance Testing section was prepared in accordance with the applicable parts of:
- Spinal System 510(k)s Guidance Document, dated May 2004
- Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements, dated February 2000

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.) ?

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

SI-BONE identified and performed verification and/or validation activities required by 21 CFR 820.30 (Design Control), including describing the methods or tests used and the acceptance criteria applied. All testing was performed by qualified individuals or test laboratories to ensure that the iFuse Bedrock Granite Implant System met the device performance and predetermined acceptance criteria. The test results demonstrate that the device is as safe and effective as the legally marketed device and does not raise different questions of safety and effectiveness than the predicate devices.

Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

K222774, (b)(4)

Add Attachment

Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.

Other Non-Clinical Evidence

Open Attachment | Attachment 12A_Performance Testing.pdf | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.1P - (b)(4) Evaluating Porous Surface Test | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.1R - (b)(4) Evaluating Porous Surface.pdf | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.2P - (b)(4) Construct (ASTM F1717) Test | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.2R - (b)(4) Construct (F1717) Testing.pdf | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.3P - (b)(4) Static Dyn Cant (F2193) Test | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.3R - (b)(4) Stat Dyn Cant (F2193) Testing iFuse | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.4P - (b)(4) Torsion (F543) Test Protocol.pdf | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.4R - (b)(4) Torsion (F543).pdf | Delete Attachment

Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.5P - (b)(4) Axial Pullout (F543) Test Protocol.pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.5R (b)(4) Axial Pullout (F543).pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.6P - (b)(4) Implant Inspection Test Protocol.pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.6R (b)(4) Implant Inspection.pdf	Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Performance Testing. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

N/A

References

Is literature referenced in the submission?	Yes	?
Add Attachment	Please add legible reprints or a summary of each article in English.	?
Open Attachment	Attachment 13A_Peck et al. - 2021.pdf	Delete Attachment
Please include a discussion of how each article is applicable to support the submission.		?

(b)(4)

Administrative Documentation

Add Attachment | General Summary of Submission/Executive Summary

Open Attachment | Attachment 14A_Executive summary.pdf | Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(l)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No. — Yes

Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it. — Yes

Add Attachment | 510(k) Summary or Statement

Open Attachment | Attachment 14B_510k Summary.pdf | Delete Attachment

Add Attachment | Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.

Open Attachment | Attachment 14C_User fees payment.pdf | Delete Attachment

Please enter in the User Fee Payment Identification Number. — (b)(4)

Show User Fee Introduction

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(l)]

I certify that, in my capacity as (Associate director) of (SI-Bone), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Date Signed: 2023-10-31

510(k)#: 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].

Verification

The following sections are complete:
Application/Submission Type
Cover Letter / Letters of Reference
Administrative Information
Device Description
Indications for Use
Classification
Predicates and Substantial Equivalence
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware & Cybersecurity/Interoperability
EMC, Wireless, Electrical, Mechanical, and Thermal Safety
Performance Testing
References
Administrative Documentation

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.
Admin Functions	FOR ADMINISTRATOR USE ONLY

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

Please submit this eSTAR PDF for review using the CDRH Portal unless your medical device is regulated by the Center for Biologics Evaluation and Research (CBER) or is a combination product where CBER is the lead. You do not need to send any documentation in physical form using mail couriers.

For CBER-regulated medical devices or for combination products where CBER is the lead, please refer to Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products for information on how to submit to CBER through the Electronic Submission Gateway.

Si-Bone, Inc.
Jayasri Prabakaran
Associate Director, Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 95050

Re: K233508
Trade/Device Name: iFuse Bedrock Granite® Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, NKB, OLO
Dated: October 31, 2023
Received: October 31, 2023

Dear Jayasri Prabakaran:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Hi Sean,

(b)(4)

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

SI-BONE logo_One color and

471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 25, 2024 12:15 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Daniel Cher <DCher@si-bone.com>; K233508@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

(b)(4)

Please confirm by COB today (1/25/2024) that you acknowledge this email that (b)(4) does not apply to the current submission (K233508).

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Tuesday, January 23, 2024 5:11 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
Appreciate this update. Thank you.

Best regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

SI-BONE logo_One color and

471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Tuesday, January 23, 2024 2:07 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

We are currently finalizing our review. While I can't give an exact date on the decision, we do not believe it will be too much longer. If we need anything more from you I'll be sure to contact you,

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Tuesday, January 23, 2024 11:11 AM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
Hope you had a good weekend. Our team is curious to know if a decision will be made by this week. So please let me know if any other information is needed from our end.

Thanks again for your timely review!

Best regards,
Jai Prabakaran
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Jayasri (Jai) Prabakaran
Sent: Friday, January 19, 2024 2:43 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov; Daniel Cher <dcher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
I have reviewed and accept the changes proposed below to the 510(k) summary.

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs
SI-BONE logo_One color and
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Friday, January 19, 2024 2:28 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 5:21 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Cc: K233508@docs.fda.gov; Daniel Cher <DCher@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510 (k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 18, 2024 11:45 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: K233508@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Thursday, January 18, 2024 12:34 PM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,
I am following up to see if you have any updates on K233508. Do you think we will be receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,
Jai Prabakaran
Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Miller, Sean <Sean.Miller@fda.hhs.gov>
Sent: Thursday, January 11, 2024 1:39:34 PM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,
Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Sent: Monday, January 8, 2024 11:28 AM
To: Miller, Sean <Sean.Miller@fda.hhs.gov>
Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hello Mr. Miller,
Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,
Jai Prabakaran, MBS (Regulatory & Clinical), RAC
Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050
Jayasri.Prabakaran@SI-Bone.com
www.SI-BONE.com

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Sent: Friday, December 29, 2023 7:15 AM
To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>
Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov>
Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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Notice: This message, including any attachments, may contain confidential and/or other proprietary business information, and is only for the review and use of the intended recipient(s). Any review or use by any others, and any distribution to any others, is strictly prohibited. If any portion of this message contains confidential information protected by the attorney client privilege and/or the attorney work product doctrine, the entire contents of this message are privileged and any mistransmission is not intended to waive such privilege. If you are not an intended recipient, please contact the sender promptly; do not disclose, use or act upon the information contained herein; and delete all copies of this message, including any attachments. SI-BONE reserves the right, to the extent permitted under applicable law, to monitor electronic communications using its systems, including this message. SI-BONE and iFuse Implant System are registered trademarks of SI-BONE, Inc.

Hi Sean,

(b)(4)

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

http://secure-web.cisco.com/1lMgHQpkM1k2cQWnucNYRhWT36ZLlWib-su5KEsSUk5GXVCuF-tkHo9JmsPHhPWjvnm1eWeOQ5Xfn8hxRslSpEt-4-2SGRQpPKUfaH4ua0N-S6UJMa4FlbozeazYQuxd0A633e42OYMNdNUizf9GYds_cKRhbaS8KxHD6oRWQaRKgnwy_neV0qvEpGe3oLdehtD31LTyQfILcLOBCekVByA/http%3A%2F%2Fwww.SI-BONE.com<http://secure-web.cisco.com/1lMgHQpkM1k2cQWnucNYRhWT36ZLlWib-su5KEsSUk5GXVCuF-tkHo9JmsPHhPWjvnm1eWeOQ5Xfn8hxRslSpEt-4-2SGRQpPKUfaH4ua0N-S6UJMa4FlbozeazYQuxd0A633e42OYMNdNUizf9GYds_cKRhbaS8KxHD6oRWQaRKgnwy_neV0qvEpGe3oLdehtD31LTyQfILcLOBCekVByA/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov>

Sent: Thursday, January 25, 2024 12:15 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>

Cc: Daniel Cher <DCher@si-bone.com>; K233508@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

(b)(4)

(b)(4)

Please confirm by COB today (1/25/2024) that you acknowledge this email that (b)(4) does not apply to the current submission (K233508).

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Tuesday, January 23, 2024 5:11 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sean,

Appreciate this update. Thank you.

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

http://secure-web.cisco.com/1lMgHQpkM1k2cQWnucNYRhWT36ZLlWib-su5KEsSUk5GXVCuF-tkHo9JmsPHhPWjvnm1eWeOQ5Xfn8hxRslSpEt-4-2SGRQpPKUfaH4ua0N-S6UJMa4FlbozeazYQuxd0A633e42OYMNdNUizf9GYds_cKRhbaS8KxHD6oRWQaRKgnwy_neV0qvEpGe3oLdehtD31LTyQfILcLOBCekVByA/http%3A%2F%2Fwww.SI-BONE.com<http://secure-web.cisco.com/1jWeP7iOdiTzaL9AZyaq9h_HyUod_5GVR59T01yfxcJWpb7adv86YUMSOmq7v7vU6-KW4rPG35pxKkzuJReOtqEpG7Wa1e8V1VPUiXO_DlM7vpw-MlUQbOxB8EOOEm61g4RUwu0rOaiiKhBudjk_MSR0SxELLXx9ckPF60c3TTfZBUhlq-ms_ZduANgMJ6JF7luv0DxfQbj3MQvC1aSQyLA/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Tuesday, January 23, 2024 2:07 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

We are currently finalizing our review. While I can't give an exact date on the decision, we do not believe it will be too much longer. If we need anything more from

you I'll be sure to contact you,

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Tuesday, January 23, 2024 11:11 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

Hope you had a good weekend. Our team is curious to know if a decision will be made by this week. So please let me know if any other information is needed from our end.

Thanks again for your timely review!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

http://secure-web.cisco.com/1lMgHQpkM1k2cQWnucNYRhWT36ZLlWib-su5KEsSUk5GXVCuF-tkHo9JmsPHhPWjvnm1eWeOQ5Xfn8hxRslSpEt-4-2SGRQpPKUfaH4ua0N-S6UJMa4FlbozeazYQuxd0A633e42OYMNdNUizf9GYds_cKRhbaS8KxHD6oRWQaRKgnwy_neV0qvEpGe3oLdehtD31LTyQfILcLOBCekVByA/http%3A%2F%2Fwww.SI-BONE.com<http://secure-web.cisco.com/1207WgAZMDcpTyLyU6tfKf0QUnLSpH9CY8uX_yFD3CQgcOhjXAultnrIYk05qAPwB6YhrwMymNus3dqebPLo4wxschb4L0sv_kRwtWPMLwusFjv4u6z4L-fgPCqIBOWBtPmRa5ONMRoaxfmNol5ckf0JhhxNqa63B_8KOZVSrGc5u-q45mKd8P47een8UULwwroRoz_KMGBT2ZO0rRvRwNg/http%3A%2F%2Fwww.SI-BONE.com>

From: Jayasri (Jai) Prabakaran

Sent: Friday, January 19, 2024 2:43 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <dcher@si-bone.com<mailto:dcher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Sean,

I have reviewed and accept the changes proposed below to the 510(k) summary.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

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Sent: Friday, January 19, 2024 2:28 PM

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Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

Thank you for your quick reply. I made a few edits to the summary you provided. Specifically:

(b)(4)

I have attached an edited version for you to review. Please confirm that these changes are acceptable to you.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Thursday, January 18, 2024 5:21 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Cc: K233508@docs.fda.gov<mailto:K233508@docs.fda.gov>; Daniel Cher <DCher@si-bone.com<mailto:DCher@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510(k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

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The main points of the revisions are as follows:

(b)(4)

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,

Sean

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Sent: Thursday, January 18, 2024 12:34 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

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Hi Sean,

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Thanks and have a good day!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

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From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 11, 2024 1:39:34 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Monday, January 8, 2024 11:28 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hello Mr. Miller,

Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,

Jai Prabakaran, MBS (Regulatory & Clinical), RAC

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

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web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Sent: Friday, December 29, 2023 7:15 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTVI/DHTVIB
WO66 RM4422
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Date: January 22, 2024

Reviewer: Sean Miller

510(k)# K233508 Subject: Traditional

Applicant: Si-Bone, Inc.	**Device Trade Name:** iFuse Bedrock Granite® Implant System
Contact Name: Jayasri Prabakaran	**Contact Title:** Associate Director, Regulatory Affairs
Correspondent Firm: Si-Bone, Inc.	**Phone:** (b)(6) **Email:** jayasri.prabakaran@si-bone.com
Received Date: October 31, 2023	**Due Date:** January 29, 2024
Pro Code(s): OUR, NKB, OLO **Class:** II **Reg #:** 888.3040	**Reg Name:** Smooth Or Threaded Metallic Bone Fixation Fastener

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K222774	OUR, NKB, OLO	iFuse Bedrock Granite® Implant System	SI-BONE, Inc.
K223494	NKB, KWP, KWQ, HBE, OLO	CD Horizon Spinal System	Medtronic
K223273	NKB, KWP, KWQ	ASTRA Spine System	SpineCraft, LLC

Recommendation

I recommend that the iFuse Bedrock Granite® Implant System is/are Substantially Equivalent (SESE)

(b)(5)

(b)(5)

(b)(5)

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Digital Signature Concurrence Table (Doc ID: 04500.16.03) This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
For each of the specific issues identified in the recommended requests to the applicant above, I and/or if applicable contributing consulting reviewer(s) (and or supervisors), have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability for requests: add all relevant numbers here, else delete that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s). I also confirm, if applicable, that contributing consulting reviewers (and or supervisors) have provided the above attestation.	
Reviewer Sign-Off	Sean Miller -S Digitally signed by Sean Miller -S Date: 2024.01.22 11:41:54 -05'00'

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,
Sean

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Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Thank you, Sean. Appreciate your quick response. We will review the IFU updates and get back to you.

Can you please let us know if this the only question or are we expecting more questions later today?

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

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To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>

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bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Thursday, January 18, 2024 12:34 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Sean,

I am following up to see if you have any updates on K233508. Do you think we will be receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

http://secure-web.cisco.com/1xxIig5LuznKhHRj87r6RaLiFWnAzfZs5opC9Lsi0mKINCs7XSF5qQTkCrZSVFMI996UHLfhHWWfMSfHDT6FLIKtc_hFZaHwJjzZU6rBUQ-bWgsKtyKngSj2m4HyMeBdLRXO8D2Z9FZ_OmwFsQBw1pFGn5x1GNUI4MjyRaHKYxGkn53hovCVooL1c7a4S6S3-kF6HHlhPnZR9qd1ozmLoTw/http%3A%2F%2Fwww.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 11, 2024 1:39:34 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Monday, January 8, 2024 11:28 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello Mr. Miller,

Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,

Jai Prabakaran, MBS (Regulatory & Clinical), RAC

Associate Director, Regulatory Affairs

[SI-BONE logo_One color and B&W_aiCC 2018_Color]

471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

http://secure-web.cisco.com/1xxIig5LuznKhHRj87r6RaLiFWnAzfZs5opC9Lsi0mKINCs7XSF5qQTkCrZSVFMI996UHLfhHWWfMSfHDT6FLIKtc_hFZaHwJjzZU6rBUQ-bWgsKtyKngSj2m4HyMeBdLRXO8D2Z9FZ_OmwFsQBw1pFGn5x1GNUI4MjyRaHKYxGkn53hovCVooL1c7a4S6S3-kF6HHlhPnZR9qd1ozmLoTw/http%3A%2F%2Fwww.SI-BONE.com<http://secure-web.cisco.com/1eORTl95jpIj_0si050H0MORh-Y3WpQKilV3-L31P1S_ZJIsFz2ziH_Z52vAqVa1q8U7X4ZJoU7_zUBE_5kPjz_v9HDP_hC0G1PabLx2Rra9JXppqX23L5D0vblSnp-7EgHaqUTPTK59dE-s9fEEn5NFhfsYkU_o52oxBzGoCIhPXNWNnCyZpmsEypA6o6KD1875oWawtzQQC-r6GepiKyg/http%3A%2F%2Fwww.SI-BONE.com>

From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Sent: Friday, December 29, 2023 7:15 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 4.3 (2023-10-02)*

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g. guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? **Blue Help Text Buttons** when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: For technical issues or bug reports please email eSubPilot@fda.hhs.gov.
For regulatory process or content questions please email:
USFDA: DICE@fda.hhs.gov
Health Canada: meddevices-instrumentsmed@hc-sc.gc.ca

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type, attachment name, or size restriction?
A: Unacceptable attachment types and names are automatically prevented. If an attachment is great than 1 GB,

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g. 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g. 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

4.3 (2023-10-02): Standard recognition number can now be used to autopopulate standard information. Texts updated

Application/Submission Type

Application Jurisdiction	(•) US FDA ( ) Health Canada

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	(•) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA

Show Application Introduction

Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	(•) Traditional ( ) Abbreviated ( ) Special

Show Application Type Introduction

Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	(•) New Application/Submission ( ) Additional Information

Cover Letter / Letters of Reference

Add Attachment	Attach your Cover Letter	?
Open Attachment	Attachment_1_Cover_Letter.pdf	Delete Attachment
Add Attachment	Attach any Letters of Reference	?

Applicant Information

Contact

Title: Ms. | Last Name: Prabakaran | First Name: Jayasri

Email: Jayasri.Prabakaran@si-bone.com | Phone Number: (b)(6)

Occupation Title: Associate Director, Regulatory Affairs

Company

Company Name: SI-Bone Inc.

Address - Line 1: 471 El Camino Real, Suite 101

Address - Line 2:

City: Santa Clara | State: CA | Zip: 95050 | Country/Region: United States

Add Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Are there prior related submissions or regulator interaction for the subject device(s)? No ?

Standards

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. A recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators request standards information be attached.

ISO	14971 Third Edition 2019-12	5-125	Delete Standard

Medical devices - Application of risk management to medical devices

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F136-13	8-377	Delete Standard

Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgica

Are you using this standard for general use, or are you declaring conformity to it?	General Use		?

Add Standard

ASTM	F1854-15	8-400	Delete Standard
Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?

Add Standard

ASTM	F1044-05 (Reapproved 2017)e1	8-112	Delete Standard
Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?

Add Standard

ASTM	F1147-05 (Reapproved 2017)e1	8-113	Delete Standard
Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?

Add Standard

ASTM	F1978-18	8-467	Delete Standard
Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber A			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?

Add Standard

ASTM	F1160-14 (Reapproved 2017)e1	8-380	Delete Standard
Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Con			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?

Add Standard

ASTM	F3001-14	8-439	Delete Standard
Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) w			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?

Add Standard

ASTM	F2193-20	11-375	Delete Standard

Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal Syst

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F543-17	11-327	Delete Standard

Standard Specification and Test Methods for Metallic Medical Bone Screws

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F1717-21	11-388	Delete Standard

Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F1798-13	11-276	Delete Standard

Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassembli

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	F3127-16	8-442	Delete Standard

Standard Guide for Validating Cleaning Processes Used During the Manufacture of Medical Devices

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	D4332-14	5-99	Delete Standard

Standard Practice for Conditioning Containers Packages or Packaging Components for Testing

Are you using this standard for general use, or are you declaring conformity to it? General Use ?

Add Standard

ASTM	D3078-02 (Reapproved 2021)e1	14-257	Delete Standard

Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?
Add Standard			
ASTM	F1980-16	14-497	Delete Standard
Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?
Add Standard			
ISO	15223-1 Fourth edition 2021-07	5-134	Delete Standard
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requir			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?
Add Standard			
ISO	17664-1 First edition 2021-07	14-578	Delete Standard
Processing of health care products - Information to be provided by the medical device manufacturer for the proce			
Are you using this standard for general use, or are you declaring conformity to it?	General Use		?
Add Standard			

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

iFuse Bedrock Granite Implant System	Multiple	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	No
Are there any direct or indirect tissue contacting components?	Yes
• Is the device or a component an implant?	Yes
Does the device use software/firmware?	No
Is the device or a component packaged as sterile?	Yes

The device/system uses or is... (choose all that apply)

- ☒ a single use device(s), non-sterile or packaged as sterile
- ☐ a single use device(s), terminal/end user sterilized
- ☐ a reusable single patient use device(s)
- ☐ a reusable multi-patient use device(s)

The environment of use of the device/system includes... (choose all that apply)

- ☒ Professional Healthcare Facility
- ☐ Home Environment
- ☐ Magnetic Resonance (MR) Environment
- ☐ Transport (Ambulatory) Environment
- ☐ Other Environment

Is the device a combination product or does a Request For Designation (RFD) / pre-RFD exist for the product?	No (most common)
Is the device electrical (battery or wall powered)?	No, the device is not electrical

Please check the attributes that are applicable to your device. If none apply, keep all unchecked.

- ☐ Medical Counter Measures Device
- ☐ Nanotechnology
- ☐ Reprocessed Single Use Device
- ☐ Animal-Derived Material(s)
- ☐ Predetermined Change Control Plan

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The iFuse Bedrock Granite Implant System consists of implants of various lengths and diameters, and

associated instrument sets for both open and minimally invasive (MIS) approaches. The titanium (Ti-6Al-4V ELI) implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the Iliac trajectories. It is designed for connection to commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm titanium alloy or cobalt chrome alloys spinal fixation rods.

The subject device is slightly smaller in diameter (9.5 mm) and is provided in lengths slightly shorter (40 mm). The surface of the sleeve is also slightly different (see below). Otherwise, the subject device is identical to previously cleared iFuse Bedrock Granite implants.

Based on feedback from surgeon customers, this 510k includes optional placement of the subject device in the S1 trajectory. This trajectory does not imply any change to the intended use nor use steps of the subject device (i.e., placement within bone and attachment to posterior spinal rods). This trajectory is commonly used by surgeons performing thoracolumbar fusions.

Note that there are no new or unique instruments required for implantation of the subject 9.5 mm iFuse Bedrock Granite Implant. The same Open (P/N 400309) and MIS (P/N 400310) Instrument Sets cleared under K220195 are also utilized for the subject 9.5 mm Granite Implant.

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	Attachment 3A_Device Description.pdf	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	Attachment 3B_Model numbers_Engg Drawings.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	Attachment 3C_Device Packaging Description.pdf	Delete Attachment

System/Kit Components and Accessories

Is the device intended to be marketed with multiple system/kit components or accessories? No ?

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

N/A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

iFuse Bedrock Granite Implant System (Multiple)

Indications for Use *(Describe)*

The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion for the following conditions:
• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
• To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments to treat progressive spinal deformities (i.e.scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the iFuse Bedrock Granite Implant System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic

image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

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."

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450). ?

Medical Specialty	Orthopedic
Regulation	888.3040 - Smooth or threaded metallic bone fixation fastener
Product Code	OUR (Class 2) - Sacroiliac Joint Fixation
Associated Product Code(s)	NKB, OLO ?

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	No
Predicate Submission Number (e.g., K210001)	K222774
Predicate Device Trade Name	iFuse Bedrock Granite Implant System
Predicate Device Primary Product Code	
Medical Specialty	Orthopedic
Regulation	888.3040 - Smooth or threaded metallic bone fixation fastener
Product Code	OUR, NKB, OLO

Add Predicate/Reference Device | Delete Predicate/Reference Device

Predicate/Reference Device

Is this a Preamendments or Exempt device without a submission number?	No
Predicate/Reference Submission Number (e.g., K210001)	K223494
Predicate/Reference Device Trade Name	CD Horizon Spinal System
Predicate/Reference Device Primary Product Code	
Medical Specialty	Orthopedic
Regulation	888.3070 - Thoracolumbosacral pedicle screw system
Product Code	NKB, KWP, KWQ

Add Predicate/Reference Device | Delete Predicate/Reference Device

Predicate/Reference Device

Is this a Preamendments or Exempt device without a submission number?	No
Predicate/Reference Submission Number (e.g., K210001)	K223273
Predicate/Reference Device Trade Name	ASTRA Spine System
Predicate/Reference Device Primary Product Code	
Medical Specialty	Orthopedic
Regulation	888.3070 - Thoracolumbosacral pedicle screw system
Product Code	NKB, KWP, KWQ

Add Predicate/Reference Device | Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

?

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Both the subject device and the primary predicate device have the same intended use for sacroiliac joint fusion and augmenting immobilization and stabilization. The proposed indications for use statement of the subject device is different from the primary predicate device; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicates.

The proposed indications for use statement for the iFuse Bedrock Granite Implant System was amended with language describing use of the subject device in the pediatric population, similar to the secondary predicate devices.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

?

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The subject device is the primary predicate. There are no changes in the subject device compared to the cleared primary predicate except for the new size offerings. The current iFuse Bedrock Granite Implant is manufactured in diameters between Ø10.5 mm – Ø13.5 mm and in lengths to accommodate the threaded screw post length range of 45 mm -120 mm. The proposed iFuse Bedrock Granite Implant will be manufactured with a diameter of Ø9.5 mm and available in lengths of 40 mm to 120 mm (in 5mm increments), thus introducing a new lower limit for diameter and length. The slightly smaller size for the subject device allows it to be placed into smaller anatomical corridors compared to the previously cleared primary predicate device.

The subject device is very similar to the predicates as follows:

• Design: the subject device and the primary predicate are threaded implants (screws) with a porous fusion sleeve; the secondary predicates are threaded implants (screws).
• Diameter: the subject device includes a smaller diameter of 9.5 mm when compared to the previously cleared primary predicate (Ø10.5 mm – Ø13.5 mm) but lies within the range of diameters offered by the secondary predicates.
• Implant lengths: the subject device includes a smaller length option of 40 mm as a line extension to the

range offered by the previously cleared primary predicate (45-120 mm). The implant length lies within the range offered by the secondary predicates.

• Surface design: the subject device's surface has a porous and fenestrated surface design similar to the primary predicate.

• Manufacturing: the subject device and the primary predicate have an implant post that is traditionally machined and a sleeve that is additively manufactured and traditionally machined.

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s). If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.	?
Open Attachment	Attachment 5_Substantial Equivalence Comparison.pdf	Delete Attachment

Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).	iFuse Bedrock Granite Implant System - Instructions for Use (IFU) 501467 Page 4 (provided as Attachment 6B).
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?	Not Evaluated
If the device(s) contains a static/permanent magnet, please specifically cite the attachment and page number where labeling includes a statement and/or contraindication regarding the risk of magnet use within 6 inches of other magnetically susceptible medical devices. Type "N/A" if not applicable.	N/A

Package Labeling

Add Attachment — Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.

Open Attachment | Attachment 6_Labeling overview and Attachment 6A Product | Delete Attachment

Package Insert / Instructions for Use

Add Attachment — Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.

Open Attachment | Attachment 6B IFU REDLINES_CLEAN.pdf | Delete Attachment

Other Labeling

Add Attachment — Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

Healthcare Professional Labeling

Open Attachment | Attachment 6C_STM REDLINES.pdf | Delete Attachment

Healthcare Professional Labeling

Open Attachment | Attachment 6C_STM Clean.pdf | Delete Attachment

Healthcare Professional Labeling

Open Attachment | Attachment 6D_Hospital Cleaning and Sterilization Instructions.pdf | Delete Attachment

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	iFuse Bedrock Granite Implant System - Instructions for Use (IFU)
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	iFuse Bedrock Granite Implant System - Instructions for Use (IFU) 501467
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	iFuse Bedrock Granite Implant System - Instructions for Use (IFU) 501467 Page 4 (provided as

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Labeling. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

N/A

Reprocessing, Sterility, and Shelf-Life

Based on the answers provided in the Device Description section, sterility information, but no reprocessing information, is needed.

Sterility

How many sterilization methods are there (maximum of 4)?	1

Sterilization Method 1

Identify the device(s) / accessory(ies) / component(s) that is sterilized.

iFuse Bedrock Granite Implant

What is the Sterilization Method?	Radiation (Est A)
What is the dose?	(b)(4)
What standard(s) were used for validation?	

• SS EN ISO 11137-1:2015 - Sterilization of Health Care Products: Radiation Sterilization - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
• SS EN ISO 11137-2:2015 - Sterilization of Health Care Products: Radiation Sterilization - Part 2: Establishing the Sterilization Dose – Method VD-Max 25

What validation method was used for the sterilization cycle?	VDmax25 (b)(4)
What is the Sterility Assurance Level (SAL)?	10^-6
If a device within the submission should be "Non-Pyrogenic," or if you are asserting a device is "Non-Pyrogenic," what is the pyrogenicity test method?	Not labeled nor required to be "Non-Pyrogenic"

Please provide a description of the packaging, the materials used, and a description of the package test methods.

(b)(4)

(b)(4)

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Reprocessing or Sterility. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

N/A

Shelf-Life

Does your device have a shelf-life?	Yes	?
What is the proposed shelf-life?	5	Years

Provide a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, provide a rationale for why testing to establish shelf-life is not applicable.

(b)(4)

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment	Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.	?

Other

Open Attachment	Attachment 7_Reprocessing_Sterility.pdf	Delete Attachment

Cleaning and Disinfection Validation

Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Tissue Contacting Products/Components/Materials

How many tissue contacting products/components/materials are there? *(See Help Text if multiple materials share the same justification for no testing.)*	1

Tissue Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

iFuse Bedrock Granite Implant (consisting of threaded screw post, fusion sleeve, tulip) and set screw

Please state the exact name and any identifiable information for the particular material used.

iFuse Bedrock Granite Implant: Ti-6Al-4V ELI per ASTM F136 and ASTM F3001
Set Screw: Titanium Ti-6Al-4V ELI per ISO 5823-3/ ASTM F136

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	(b)(4)

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Additional Biocompatibility testing is not needed since the implant materials and manufacturing/processing are identical to the predicate.

Are the listed components in contact with intact skin only AND are all the component materials included in Attachment G, Section B of the FDA Biocompatibility Guidance?	No
Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Implant Device: Tissue/Bone
Duration of Contact	> 30 days (i.e., permanent)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that

we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** If tests are conducted under the Accreditation Scheme for Conformity Assessment (ASCA), select the ASCA option and attach ASCA summary test reports. For instances where the complete test report should be provided in addition to the ASCA Summary Test Report, please refer to the ASCA Guidance for more information.

Cytotoxicity | Sensitization | Irritation | Acute Systemic & Pyrogenicity | Subacute/Subchronic | Genotoxicity | Implantation | Chronic | Carcinogenicity

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	(b)(4) ?
Identify the test article used in testing.	iFuse Bedrock Granite Implant and set screws

Extraction Conditions

Test Article Extraction Ratio	(b)(4) ?
Extraction Vehicle(s)	(b)(4)
Extraction Conditions	(b)(4) ?
Was the test extract diluted, filtered, or was the pH adjusted?	(b)(4)
Study Controls	(b)(4)
Extract/Test Article is clear (i.e., not cloudy/turbid, no particulates, no color change, no swelling/degradation of the test article)?	(b)(4)
Extract Storage Conditions	(b)(4)

Methods

Test System	(b)(4)
Assessment Times After Treatment	(b)(4)
Was the following scale used for test extract, reagent control, negative control and positive control? 0: discrete intracytoplasmic granules & no lysis 1: occasional lysed cells (0-20% cells rounded, loose) 2: no extensive cell lysis (20-50% cells rounded) 3: 50-70% lysis (50-70% cells rounded) 4: nearly complete destruction of cell layer (>70% lysis)	(b)(4)
Were there deviations?	(b)(4)

Results

Were there any cell abnormalities?	(b)(4)
Were cytotoxicity scores in the controls as expected (e.g., reagent and/or negative are noncytotoxic, positive is cytotoxic)?	(b)(4)

Conclusion

Cytotoxic Potential	(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Close Tab

Acute Systemic Toxicity Testing & Material Mediated Pyrogenicity Testing

Acute Systemic Toxicity Testing

Was Acute Systemic Toxicity testing conducted?	(b)(4)

Material Mediated Pyrogenicity Testing

Was Material Mediated Pyrogenicity testing conducted?	(b)(4)

Specific questions for these tests do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Acute Systemic Toxicity and and Material Mediated Pyrogenicity be assessed. If testing is

performed, we recommend it be conducted per ISO 10993-11 for Acute Systemic Toxicity and per ISO 10993-11 and USP <151> for Material Mediated Pyrogenicity. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Subacute/Subchronic Toxicity Testing

Was Subacute/Subchronic Toxicity testing conducted? (b)(4)

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Subacute/Subchronic Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Genotoxicity Testing

Was Genotoxicity Toxicity testing conducted? (b)(4)

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Genotoxicity Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-3 and ISO/TR 10993-33. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Implantation Testing

Was Implantation Toxicity testing conducted? | * No

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Implantation Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-6. You may also like to consult ASTM F981-04, F1408-97, F1983-99, and F763-05 for more information, as well as the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Chronic Toxicity Testing

Was Chronic Toxicity testing conducted? | (b)(4)

Specific questions for this test do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Chronic Toxicity be assessed. If testing is performed, we recommend it be conducted per ISO 10993-11. You may also like to consult the FDA supplemental information sheet for this testing. Please provide a test report in an attachment in the Biocompatibility Reports and Documentation section below, or provide a justification for why testing was not conducted in the Comments below.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Carcinogenicity Assessment

Was Carcinogenicity assessment conducted? | (b)(4)

Specific questions for this endpoint do not exist yet in this template or the FDA reviewer's Smart Templates. We recommend Carcinogenicity be assessed. If in rare cases testing is needed, please contact FDA to discuss your proposed methods prior to initiation of the studies to ensure that the studies will be adequately designed to address FDA's concerns. Use of the Q-submission process may be helpful. Please provide the carcinogenicity assessment, or if applicable, the carcinogenicity test report in an attachment in the Biocompatibility Reports and Documentation section below. Please also see the Biocompatibility Guidance.

Comments

Please summarize justifications, why testing was not conducted, etc, below.

(b)(4)

Close Tab

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.	
Open Attachment	Attachment 8_Biocompatibility.pdf	Delete Attachment

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, no software, cybersecurity, or interoperability information is needed.

EMC, Wireless, Electrical, Mechanical, and Thermal Safety ?

Based on the answers provided in the Device Description section, no EMC or wireless technology information is needed. You should still address Mechanical and Thermal safety testing in the textbox below.

Electrical, Mechanical, and Thermal (EMT) Safety Summary

Please summarize the Electrical, Mechanical and Thermal Safety Testing of your device, or summarize why testing was not needed. Please ensure any standards used here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence). Attach any supporting documentation for each standard used in your testing to the EMC, Wireless, & EMT Documentation section below. ?

N/A

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.

Performance Testing

Was Bench Testing used in order to support this submission?	Yes
Was Animal Testing used in order to support this submission?	No
Was Clinical Testing used in order to support this submission?	No

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.

SI-BONE performed the following performance tests:
• Static and Dynamic Cantilever Testing per ASTM F2193
• Static Torsion Testing per ASTM 543
• Static Axial Pull out Testing per ASTM 543
• Characterizing the Porous Surface Bedrock Granite Test (Static Shear, Static Fatigue, Static Tensile, Abrasion Properties)
• Construct Testing per ASTM F1717 (Static Axial Compression)

The test results demonstrate that the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.

The Performance Testing section was prepared in accordance with the applicable parts of:
• Spinal System 510(k)s Guidance Document, dated May 2004
• Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements, dated February 2000

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.)

N/A

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

SI-BONE identified and performed verification and/or validation activities required by 21 CFR 820.30 (Design Control), including describing the methods or tests used and the acceptance criteria applied. All testing was performed by qualified individuals or test laboratories to ensure that the iFuse Bedrock Granite Implant System met the device performance and predetermined acceptance criteria. The test results demonstrate that the device is as safe and effective as the legally marketed device and does not raise different questions of safety and effectiveness than the predicate devices.

Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.

K222774, (b)(4)

Add Attachment

Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.

Other Non-Clinical Evidence		
Open Attachment	Attachment 12A_Performance Testing.pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.1P - (b)(4) Evaluating Porous Surface Test	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.1R - (b)(4) Evaluating Porous Surface.pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.2P - (b)(4) Construct (ASTM F1717) Test	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.2R - (b)(4) Construct (F1717) Testing.pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.3P - (b)(4) Static Dyn Cant (F2193) Test	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.3R - (b)(4) Stat Dyn Cant (F2193) Testing iFuse	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.4P - (b)(4) Torsion (F543) Test Protocol.pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.4R - (b)(4) Torsion (F543).pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.5P - (b)(4) Axial Pullout (F543) Test Protocol.pdf	Delete Attachment
Other Non-Clinical Evidence		
Open Attachment	Attachment 12B.5R - (b)(4) Axial Pullout (F543).pdf	Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.6P (b)(4) Implant Inspection Test Protocol.pdf | Delete Attachment

Other Non-Clinical Evidence

Open Attachment | Attachment 12B.6R (b)(4) Implant Inspection.pdf | Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Performance Testing. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

N/A

References

Is literature referenced in the submission?	Yes	?
Add Attachment	Please add legible reprints or a summary of each article in English.	?
Open Attachment	Attachment 13A_Peck et al. - 2021.pdf	Delete Attachment
Please include a discussion of how each article is applicable to support the submission.		?

(b)(4)

Administrative Documentation

Add Attachment	General Summary of Submission/Executive Summary
Open Attachment	Attachment 14A_Executive summary.pdf — Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(l)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.	Yes
Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	Yes

Add Attachment	510(k) Summary or Statement
Open Attachment	Attachment 14B_510k Summary.pdf — Delete Attachment
Add Attachment	Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.
Open Attachment	Attachment 14C_User fees payment.pdf — Delete Attachment

Please enter in the User Fee Payment Identification Number. **(b)(4)**

Show User Fee Introduction

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(l)]

I certify that, in my capacity as (Associate director) of (SI-Bone), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Jayasri Prabakaran	Digitally signed by Jayasri Prabakaran Date: 2023.10.31 11:08:54 -07'00'

Date Signed: 2023-10-31

510(k)#: 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].

Verification

The following sections are complete:
Application/Submission Type
Cover Letter / Letters of Reference
Administrative Information
Device Description
Indications for Use
Classification
Predicates and Substantial Equivalence
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware & Cybersecurity/Interoperability
EMC, Wireless, Electrical, Mechanical, and Thermal Safety
Performance Testing
References
Administrative Documentation

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.
Admin Functions	FOR ADMINISTRATOR USE ONLY

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

Please submit this eSTAR PDF for review using the CDRH Portal unless your medical device is regulated by the Center for Biologics Evaluation and Research (CBER) or is a combination product where CBER is the lead. You do not need to send any documentation in physical form using mail couriers.

For CBER-regulated medical devices or for combination products where CBER is the lead, please refer to Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products for information on how to submit to CBER through the Electronic Submission Gateway.

Form Approved: OMB No. 0910-0511 Expiration Date: October 31, 2024. 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)
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: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

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

SI-BONE INC
471 El Camino Real, Suite 101
Santa Clara
CA 95050
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****6351

2. CONTACT NAME
Daniel Cher
2.1 E-MAIL ADDRESS
dcher@si-bone.com
2.2 TELEPHONE NUMBER (include Area code)
650-8624942
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
[ ] De Novo Request

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)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] 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
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 05-Oct-2023

Form FDA 3601 (07/22)

"Close Window" Print Cover sheet

8. Biocompatibility

8.1 iFuse Bedrock Granite Implants

8.1.1 Tissue-Contacting Components and Classification

(b)(4)

8.1.2 iFuse Bedrock Granite Implant Biological Safety Evaluation

(b)(4)

Table 8-2: Summary of Biocompatibility evaluation information for iFuse Bedrock Granite Implants per 10993-1 and FDA Guidance (September 4, 2020) - Required Biological Endpoints

(b)(4)

(b)(4)

8.1.3 iFuse Bedrock Granite Implant Biological Evaluation Conclusion

(b)(4)

Based on the results of the Biological Safety Evaluation, the iFuse Bedrock Granite Implants are considered biologically safe for use in humans and have demonstrated adequate conformity with ISO 10993-1:2018 and FDA Guidance *Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process*, September 4, 2020.

8.2 iFuse Bedrock Granite Instruments

(b)(4)

8.2.1 Components and Classification

(b)(4)

8.2.2 Biological Safety Evaluation for the iFuse Bedrock Granite Instrument Sets

(b)(4)

8.2.3 Results of the Biological Risk Assessment for the iFuse Bedrock Granite Instrument Sets

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Instructions for Use – iFuse Bedrock Granite® Implant System

℞ ONLY

DEVICE DESCRIPTION

The iFuse Bedrock Granite® Implant System consists of implants of various lengths and diameters, and associated instruments sets (for both Open and minimally invasive [MIS] approaches). The titanium (Ti6Al4V ELI) implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to a commercially available pedicle screw fixation system in both the SAI and the Iliac trajectories. It is designed for connection to compatible commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm diameter circular titanium alloy or cobalt chrome alloy spinal fixation rods. Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

INDICATIONS FOR USE

The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments to treat progressive spinal deformities (i.e.scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the iFuse Bedrock Granite Implant System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

ADDITIONAL COMPATIBILITY INFORMATION

Compatible pedicle screw system rods include all the conditions listed below:

1. 5.5- or 6.0-mm in diameter
2. Cross section is circular and non-threaded
3. Made of:
    - Titanium alloy (Ti-6Al-4V ELI per ASTM F136),

- Cobalt chrome (Co-28Cr-6Mo per ASTM F1537 or 35Co-35Ni-20Cr-10Mo per ASTM F562)

4. Not additively manufactured
5. Not coated with additional materials (e.g., Hydroxyapatite)

Note: Anodization (color or type II) does not alter the material

CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

Please refer to the Instructions for Use of the connected pedicle screw system for a complete list of all warnings, precautions and possible adverse events associated with its use.

CONTRAINDICATIONS

The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon.

- Deformities or anatomic variations that prevent or interfere with iFuse Bedrock Granite Implant placement.
- Tumor of sacral or ilial bones that could adversely affect implant placement.
- Active infection at treatment site.
- Allergy to metal components.
- Use of incompatible materials from other systems.

WARNINGS

1. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
2. Inspect implants and instruments for damage prior to use. Do not use any component from an opened or damaged package or use any device that appears damaged or worn; do not attempt to repair damaged devices. Use of damaged devices may result in patient injury.
3. Do not reuse implants under any circumstances. A used implant should be discarded.
4. Do not use implants after the expiration date, as use of expired devices may result in patient harm.
5. Care should be used during surgical procedures to prevent damage to the device(s), and injury to the patient.
6. iFuse Bedrock Granite Implants have porous surfaces that are designed to integrate with bone (i.e., bone ongrowth and ingrowth). Growth of bone onto/into the implants may make late removal of implants challenging. Trephines, chisels or other instruments may be needed to separate the implant from surrounding bone to allow removal.
7. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
   CAUTION: This device has not been tested with all FDA-cleared spinal rods. Performance may vary.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury.

PRECAUTIONS

1. The iFuse Bedrock Granite Implant System should only be used by physicians familiar with pelvic fixation techniques as illustrated in the SI-BONE iFuse Bedrock Granite Surgical Technique Manual.
2. Consult the Pedicle Screw System Surgical Technique Manual for use instructions and warnings, precautions, and recommendations relevant to the pedicle screw system.
3. Pay careful attention to selection of implant size. Pre- operative X-rays and/or CT scan may be helpful in selecting implant size.
4. Select implant size sufficient to ensure adequate fixation within the pelvis given the planned trajectory and pelvic anatomy.
5. Use sterile technique when handling the implant and during the procedure to maintain sterility and minimize risk of infection.
6. Care should be used in the handling and storage of the implants. Instruments should be protected during storage and from corrosive environments.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

MRI SAFETY INFORMATION

The iFuse Bedrock Granite Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the iFuse Bedrock Granite Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

RISKS/POSSIBLE ADVERSE EVENTS

As with other surgical procedures used to treat SI joint conditions the general risks and possible adverse events associated with the iFuse Bedrock Granite Implant System surgical procedure include, but are not limited to, the following:

1. Adverse reactions to anesthesia
2. Hemorrhage
3. Irritation or injury to local tissues such as bone, muscle, subcutaneous tissues and skin
4. Bone growth leading to local symptoms
5. Injury to spinopelvic structures (e.g., nerve root, dura, hip joint, bowel, genitourinary structures, and/or blood vessels)
6. Infection of the wound, deep infection, peritonitis, wound dehiscence
7. Thrombosis, thrombophlebitis or embolism (pulmonary or systemic)
8. Injury or delay due to broken instruments with/without retained fragments
9. Death

Potential risks and possible adverse events specifically associated with the iFuse Bedrock Granite Implant System include, but are not limited to the following:

1. Irritation or injury to local tissues such as bone, muscle, subcutaneous tissues and skin
2. Injury to spinopelvic structures (e.g., nerve root, dura, hip joint, bowel, genitourinary structures, and/or blood/lymphatic vessels)
3. Allergic reaction to components of implants or instruments
4. Delayed union, malunion, non-union of SI joint or spine motion segments
5. Infection
6. Dislodgement of bone into the foramen
7. Implant dissociation, breakage, migration or loosening
8. Set screw loosening with rod dissociation
9. Local tissue reaction to wear debris
10. Fracture of sacrum and/or ilium
11. Loss of spinal curvature correction

HOW SUPPLIED

The iFuse Bedrock Granite Implant is provided sterile; do not re-sterilize.
The instrumentation and additional set screws are provided separately, non-sterile, and must be cleaned and steam sterilized prior to use following the *SI-BONE iFuse Family of Instruments Hospital Cleaning and Sterilization Instructions (300065)*.

STORAGE/HANDLING

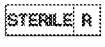
1. Store instruments and implants away from extremes in temperature and humidity.
2. Handle the implant and instruments with care to prevent damage to the surface finish.

DIRECTIONS FOR USE

1. For detailed information, refer to the relevant SI-BONE Surgical Technique Manual (300961-US) available at www.si-bone.com/label prior to use of the iFuse Bedrock Granite Implant System.
2. When used in conjunction with a pedicle screw system, the iFuse Bedrock Granite Implants may be placed in either a sacral alar iliac or iliac trajectory for pelvic fixation.

   NOTE: If SI joint fusion is desired, iFuse Bedrock Granite should be placed across the SI joint in the sacral alar iliac trajectory along with a second sacroiliac fusion promoting device placed across the joint.

GRAPHIC SYMBOLS GLOSSARY

	Caution, refer to instructions for use
	Sterilized using irradiation
	Non-sterile (instruments sets including additional set screws provided in instrument sets)
	Batch code
	Use-by date
	Catalog number
	Do not reuse (iFuse Bedrock Granite Implant and Set Screw, Bedrock Granite MIS Guidewire Sharp)
	Do not resterilize (iFuse Bedrock Granite Implant)
	Do not use if package is damaged and consult instructions for use
	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
	Consult instructions for use or electronic instructions for use & symbols glossary www.si-bone.com/label
	Manufacturer
	Date of manufacture
	Medical device

Manufactured for:
SI-BONE, Inc.
471 El Camino Real,
Suite 101
Santa Clara, CA 95050 USA

Customer Service:
Complaints and adverse events relating to use of the procedure and/or device should be reported to SI-BONE, Inc.
USA: 408-207-0700 or Toll Free: 855-884-3873
Email: www.si-bone.com

Patents: www.si-bone.com

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Mechanical performance of thoracolumbosacral pedicle screw systems: An analysis of data submitted to the Food and Drug Administration

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ARTICLE INFO

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Mechanical testing
Spinal devices
Posterior instrumentation
Posterior spinal fixation systems
ASTM F1717
ASTM F1798
ASTM F543

ABSTRACT

Thoracolumbosacral pedicle screw systems (TPSSs) are spinal implants commonly utilized to stabilize the spine as an adjunct to fusion for a variety of spinal pathologies. These systems consist of components including pedicle screws, rods, hooks, and various connectors that allow the surgeon to create constructs that can be affixed to a wide range of spinal anatomy. During the development and regulatory clearance process, TPSSs are subjected to mechanical testing such as static and dynamic compression bending per ASTM F1717, axial and torsional grip testing per ASTM F1798, and foam block pullout testing per ASTM F543. In this study, design and mechanical testing data were collected from 200 premarket notification (510(k)) submissions for TPSSs submitted to FDA between 2007 and 2018. Data were aggregated for the most commonly performed mechanical tests, and analyses were conducted to assess differences in performance based on factors such as component type, dimensions, and materials of construction. Rod material had a significant impact on construct stiffness in static compression bending testing with cobalt chromium rods being significantly stiffer than titanium rods of the same diameter. Pedicle screw type had an impact on compression bending yield strength with monoaxial screws having significantly higher yield strength as compared to polyaxial or uniplanar screws. Axial and torsional gripping capacities between components and the rods were significantly lower for cross-connectors than the other component types. The aggregated data presented here can be utilized for comparative purposes to aid in the development of future TPSSs.

1. Introduction

Thoracolumbosacral pedicle screw systems (TPSSs) are spinal implants commonly utilized to treat adult and pediatric patients for a range of spinal pathologies including deformities, trauma, and degenerative conditions. TPSSs are intended to provide stability and help restore or maintain alignment of the spinal column while fusion develops. Pedicle screw use has been reported since the middle of the 20th century and gained popularity in the U.S. in the 1980s and 1990s, with orthopedic surgeons such as Paul Harrington, Raymond Roy-Camille, and Arthur Steffee making key contributions to their development (Gaines, 2000; Harrington and Tullos, 1969; Roy-Camille et al., 1986; Steffee et al., 1986).

TPSSs have since evolved to allow greater surgical flexibility and precision in anchor placement, while facilitating more complex instrumentation systems to address wider variation of spinal pathologies. TPSSs usually utilize rigid rods as longitudinal members to connect pedicle screws implanted at various spinal levels (Fig. 1). Pedicle screws are inserted from a posterior approach, most commonly along the axis of the pedicle into the vertebral body to anchor the TPSS construct to the spine. Pedicle screws are often offered in three varieties, defined by the freedom of the screw head (commonly called the "tulip") with respect to the screw shank: monoaxial (non-articulating), polyaxial, and uniplanar. Polyaxial designs typically allow for a 360° cone of angulation of the screw tulip with respect to the screw shank to allow better alignment of components prior to rigid connection to the rod, while uniplanar designs only allow for such angulation in one plane. Hooks offer an additional option for anchorage by attaching to posterior structures such

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as the lamina, pedicle, or transverse processes. Lateral connectors (LC) offer the ability to connect anchors to anatomy that extends laterally from the TPSS construct, such as the ilium. Rod-to-rod connectors (R-R) connect rods to one another to extend previously implanted constructs, or to connect a TPSS to a cervical system. Cross-connectors (CC) are used to connect bilaterally placed rods to add stability to a construct. Used together, these components create various configurations which accommodate a wide range of patient conditions and anatomical variations.

TPSSs typically restrain movement of two or more vertebrae while a bony fusion develops between the immobilized vertebrae. TPSSs must therefore be strong enough to endure *in vivo* loads and stabilize the spine during this process. To evaluate the mechanical strength of TPSSs prior to clinical use, spinal device manufacturers conduct static and dynamic mechanical testing. *ASTM F1717 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model* contains methods for testing TPSS constructs in a vertebrectomy model that simulates worst-case bending moments in the absence of anterior column support. *ASTM F1798 Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants* contains methods used to evaluate the interconnection strength between TPSS components and the rods. *ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws* contains methods used to compare fixation strengths of screws. In order to gain marketing clearance of a new TPSS in the U.S., the results from these tests are provided to FDA as part of a premarket notification (510(k)) submission. A critical aspect of a 510(k) submission for a TPSS is the comparison of design and performance testing between the new device and a legally marketed predicate device to demonstrate "substantial equivalence".

The objectives of this study are to: (1) present aggregated design characteristics and mechanical testing results of FDA-cleared TPSSs to provide designers and manufacturers an envelope of geometries and performance, and (2) provide comparisons to better understand the effect on mechanical properties of common materials, dimensions, and component types.

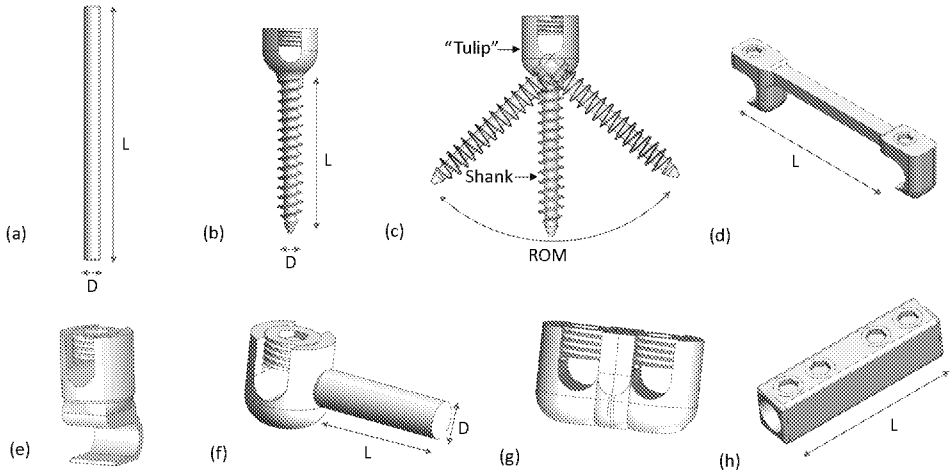

Fig. 1. Common components of thoracolumbosacral pedicle screw systems: (a) rod, (b) monaxial pedicle screw, (c) polyaxial pedicle screw, (d) cross-connector, (e) hook, (f) lateral connector, (g) parallel rod-to-rod connector, and (h) axial rod-to-rod connector. Dimensions are shown that correspond with those provided Table 1.

2. Methods

TPSS dimensions, materials, and mechanical testing data were collected from 200 510(k)s (from 115 different submitters) submitted to FDA between 2007 and 2018. Mechanical tests were performed on components determined to be worst-case (e.g., weakest and/or lowest stiffness). This study was limited to rigid TPSSs; semi-rigid[1] TPSSs were not included. Within the 200 submissions, 732 mechanical tests (each test performed on 5 or more specimens) conducted at 54 different laboratories, met the criteria for inclusion in this analysis.

2.1. Component dimensions and materials

Component dimensions and materials were collected for pedicle screws (length, major diameter, polyaxial range of motion), rods (length, diameter), CCs (span distance), hooks (material only), LCs (length, diameter of the rod extension), parallel R-Rs (material only), and axial R-Rs (length), as shown in Fig. 1.

2.2. Mechanical testing per ASTM F1717, ASTM F1798, and ASTM F543

Static and dynamic compression bending and static torsion test results per ASTM F1717 were collected. ASTM F1717 testing involves fixation of a TPSS construct with a 76 mm active length (to approximate fixation across two lumbar functional spinal units) to a test block with a 40 mm moment arm from the screw insertion location to the load application point (Fig. 2). For compression bending testing, compression loads are applied by an actuator through hinge-pins to the anterior portion of the test blocks, which results in compression loads and bending moments applied to the construct (Fig. 2**(a)**). Torsion testing involves a similar setup with torsional loads applied by an actuator about the z-axis via the same hinge-pin connection (Fig. 2**(b)**). For each static test, average stiffness, yield strength, and ultimate strength were collected. Yield and ultimate strength values were not included if yield or ultimate behavior was not observed as previously described (Peck et al., 2017). For dynamic compression bending, the highest runout load (defined as the load at which 5 million cycles are achieved without construct failure) and the lowest cyclic load that resulted in a failure prior to runout were collected. Fatigue test results were not included in this analysis if the lowest failure load was greater than 1.25x the highest runout load, representing precision as defined in ASTM F1717.

ASTM F1798 involves testing of interconnections between

[1] Semi-rigid TPSSs are defined in 21 CFR 888.3070 as "systems that contain one or more of the following features (including but not limited to): Non-uniform longitudinal elements, or features that allow more motion or flexibility compared to rigid systems."

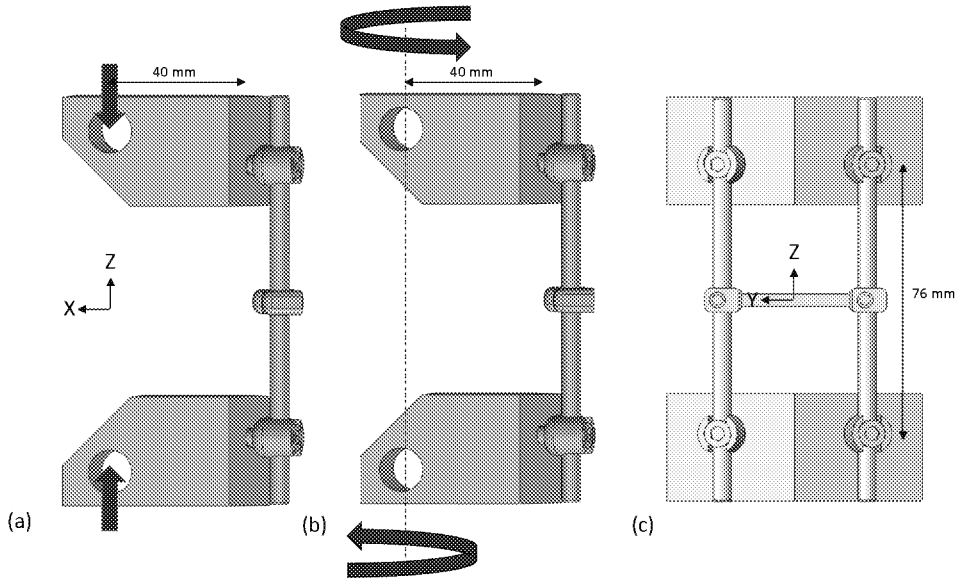

Fig. 2. ASTM F1717 test constructs showing (a) compression bending loading in lateral view, (b) torsional moment in lateral view, and (c) posterior test construct view.

components (pedicle screws, hooks, R-Rs, CCs, and LCs) and the rod. Static axial and torsional grip, static and dynamic flexion–extension, and static tulip-shank dissociation test results were collected per ASTM F1798 (Fig. 3). In axial grip testing, load is applied to the component along the axis of the rod to determine the force required to cause slip of the component along the rod (Fig. 3**.a.**). Similarly, torsional grip testing measures the torque required to cause a component to rotate about the axis of the rod (Fig. 3**.b**). Axial and torsional gripping capacities were collected and stratified by component type (pedicle screw, hook, LC, R-R, CC), with gripping capacity defined by ASTM F1798 as, "the maximum applied load or moment across the interconnection mechanism within the first 1.5 mm of permanent displacement or 5° of permanent rotation between the connected components." Static and dynamic flexion–extension tests per ASTM F1798 were performed on pedicle screws and involves application of a static or fully-reversed cyclic load on the screw shank at a 25 mm offset from the rod (Fig. 3**.c. and d**). Yield loads for static and runout loads for dynamic flexion–extension tests were calculated using the same methodology and exclusions as the ASTM F1717 testing described above, with the exception that successful dynamic runout is defined per ASTM F1798 as reaching 2.5 million cycles without failure. Pedicle screw tulip-shank dissociation testing measures the ultimate load necessary to separate a screw tulip from the screw shank in both neutral and maximum angulation (Fig. 3**.e and f**).

Axial pullout test results were collected per ASTM F543 (Fig. 3**.e**). Axial pullout testing involves insertion of a pedicle screw into a polyurethane foam test block intended to mimic the properties of bone. Test results were aggregated for tests that utilized an insertion depth of 20 mm and Grade 15 foam (the most common test configuration among the data collected). The ultimate load necessary to pull the screw out of the foam block was recorded. Failure modes for all tests were collected based on descriptions and/or failure mode pictures in test reports.

2.3. Data analysis

To maintain confidentiality, all data presented were aggregated, de-identified, and the lowest and highest 5% of results from each data set

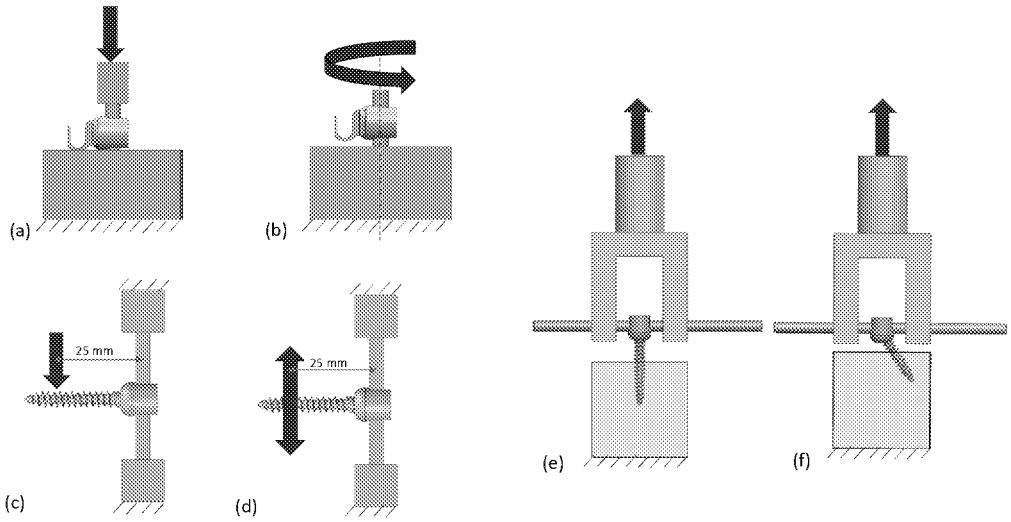

Fig. 3. ASTM F1798 and F543 test setups showing: (a) axial grip, (b) torsional grip, (c) static flexion–extension, (d) dynamic flexion–extension with fully-reversed cyclic loading, (e) neutral angle screw tulip-shank dissociation (with rigid screw shank fixation) or foam block pullout test (with Grade 15 polyurethane foam test block), and (f) maximum angle screw tulip-shank dissociation.

are excluded. The 5th percentile of the minimum dimension and the 95th percentile of the maximum dimension were calculated for various component dimensions as shown in Fig. 1. Additionally, prevalence of component material was calculated as a percentage of the total number of components. For construct testing results per ASTM F1717, each mechanical performance parameter (static testing: stiffness, yield strength, and ultimate strength; dynamic testing: runout load) was aggregated and the 5th, 25th, 50th, 75th, and 95th percentiles were calculated. Similar data aggregation and percentile calculations were performed for the ASTM F1798 and ASTM F543 tests. The coefficient of variation (standard deviation divided by mean), a measure of intra-laboratory variability, was calculated for each static test parameter for each individual test. The coefficient of variation data were then aggregated for each static test parameter, and the median and interquartile range were calculated. Sample sizes for a given parameter less than n = 10 were considered insufficient to present the full range of percentiles (or interquartile range for coefficient of variation). In these cases, only median values are reported. The failure mode prevalence was calculated as a percentage of occurrence for each test.

A two-way ANOVA with Tukey post-hoc pairwise analysis ($\alpha = 0.05$) was used to determine the effect of construct parameters (screw type, screw diameter, rod material, rod diameter) on mechanical properties from ASTM F1717 static and dynamic compression bending and static torsion. Similar analysis was performed to determine the effect of component type (screw, LC, R-R, and CC) on axial and torsional gripping capacity per ASTM F1798 ($\alpha = 0.05$). In order to minimize variability, the effect of screw type and screw diameter were additionally evaluated for static and dynamic compression bending per ASTM F1717 in the subset of tests that utilized 5.5 mm Ti-Alloy rods. As the datasets were determined to be nonparametric, the log transformation was used to satisfy normality requirements and verified with the Shapiro-Wilk test ($\alpha = 0.05$). A minimum sample size of five was required for all construct parameter subgroups to satisfy variance requirements and verified with the plots of residuals versus fitted values.

3. Results

3.1. Device design

Table 1 shows the 5th-95th percentile dimensional ranges for the various component types submitted in the 200 submissions. Most components in each category were manufactured from titanium alloy (Ti-Alloy). Alternate materials included cobalt chromium (CoCr), commercially pure titanium (CP-Ti), and stainless steel.

3.2. Mechanical test results

Table 2 lists the range of mechanical testing results for ASTM F1717 static compression bending, static torsion, and dynamic compression bending. Table 3 lists the range of mechanical test results for axial and torsional gripping capacity, static and dynamic flexion–extension, tulip-shank dissociation, and screw pullout testing per ASTM F1798 and ASTM F543. The median and interquartile range of the coefficient of variation for each static test parameter are also listed in Tables 2 and 3 to provide an understanding of expected intra-laboratory variability when performing these tests. Table 4 lists the distributions of failures modes observed for each test. Note that failure mode percentages often do not add up to 100% as multiple failure modes can be observed during a single test.

For static compression bending per ASTM F1717, screw diameter ($p < 0.01$), rod material ($p < 0.01$), and rod diameter ($p < 0.01$) all significantly affected construct stiffness (n = 183). Constructs with CoCr rods were stiffer than constructs with Ti-Alloy rods or CP-Ti rods ($p < 0.01$) (Fig. 4). However, screw type had no effect on stiffness ($p = 0.10$). Screw type ($p < 0.01$), screw diameter ($p < 0.01$), rod material ($p = 0.02$), and rod diameter ($p < 0.01$) all significantly affected construct

Table 1
Thoracolumbosacral Pedicle Screw System Component Characteristics.

Component Type	Dimension	Minimum[a]	Maximum[b]	Materials
Rods	Diameter (mm)	4.5	6.35	Titanium Alloy (70%), Cobalt Chromium (18%), CP Titanium (8.5%), Stainless Steel (3.5%)
	Length (mm)	20	600	
	Major Diameter (mm)	4	10.5	
Screws	Length (mm)	20	130	Titanium Alloy (95%), Stainless Steel (3.5%), Cobalt Chromium (1.5%)
	Polyaxial Range of Motion (deg)	25	90	
Cross-Connectors	Rod-to-Rod Span Length (mm)	13	100	Titanium Alloy (95%), Stainless Steel (4%), Cobalt Chromium (1%)
	Diameter (mm)	4.5	6.35	Titanium Alloy (93.5%), Stainless Steel (3.2%), Cobalt Chromium (1.6%), CP Titanium: (1.6%)
Lateral Connectors	Length (mm)	10	110	
Rod-to-Rod Connectors	Axial Connector Length (mm)	21	100	Titanium Alloy (100%)

[a] 5th percentile of the minimum dimension submitted.
[b] 95th percentile of the maximum dimension submitted.

Table 2
ASTM F1717 mechanical testing results.

		Count	Percentile					Coefficient of Variation (median [IQR])
			5th	25th	50th	75th	95th	
Static Compression Bending	Stiffness (N/mm)	187	18.9	27.9	31.5	36.0	48.4	0.028 [0.008, 0.044]
	Yield (N)	168	203	241	293	350	472	0.048 [0.027, 0.070]
	Ultimate (N)	31	255	364	429	500	671	0.054 [0.037, 0.106]
Static Torsion	Stiffness (N-m/deg)	98	1.2	1.7	2.4	3.0	4.6	0.067 [0.038, 0.101]
	Yield (N-m)	86	5.3	7.4	9.7	11.9	20.0	0.053 [0.035, 0.089]
	Ultimate (N-m)	15	12.6	20.4	33.7	46.0	143.1	0.069 [0.028, 0.094]
Dynamic Compression Bending	Runout (N)	90	120	168	194	214	254	–

yield strength (n = 169). The same trends observed for stiffness within rod material and rod diameter were observed for yield strength. Screw type also had a significant effect on construct yield strength; constructs with monoaxial screws had higher yield strength than constructs with polyaxial or uniplanar screws ($p < 0.01$) (Fig. 5). For dynamic compression bending, the two-way ANOVA did not detect any effect of screw type, screw diameter, rod material, and rod diameter on runout load ($p > 0.05$). For the follow-up analysis among the subset of constructs with 5.5 mm Ti-Alloy rods, no effect of screw type or screw diameter was detected on runout load.

For static torsion, screw diameter ($p < 0.01$), rod material ($p < 0.01$), and rod diameter ($p < 0.01$) all significantly affected construct stiffness (n = 98). The same trends observed in static compression bending stiffness for the effect of screw diameter, rod material, and rod diameter were observed for static torsional stiffness. Screw type had no effect on stiffness ($p = 0.07$). Screw diameter was the only construct parameter that affected torsional yield strength (n = 84). Constructs with 4.0 mm diameter screws had lower yield strength than constructs with 4.5 or 5.0 mm screws ($p < 0.01$).

Similar trends between component types were found for both axial and torsional gripping capacity (Fig. 6). Screws, LCs, and R-Rs had higher axial and torsional gripping capacity than CCs. R-Rs also had higher axial and torsional gripping capacity than screws. All pairwise comparisons of axial and torsional gripping capacity resulted in $p < 0.01$.

4. Discussion

This study was conducted to aggregate and analyze design and mechanical testing data from 510(k) submissions for TPSSs. The mechanical performance data presented can be utilized during the development of future TPSSs (Tables 2, 3, and 4). The primary purpose of these tests is to provide a repeatable means to compare mechanical performance across different systems, but the tests are not necessarily designed to replicate complex spinal loading conditions expected *in vivo* (Graham et al., 2014). For example, median static compression bending yield load and dynamic compression bending runout loads calculated in the present study were 293 N and 194 N, respectively, which is lower than estimated compressive forces in the lumbar spine during activities of daily living (~500 to 1000 N) (Dreischarf et al., 2016; Nachemson, 1981; Schultz et al., 1982). TPSSs cannot resist the expected *in vivo* axial loads during ASTM F1717 compression bending tests because these tests are conducted without anterior support such as anterior anatomy and/or additional spinal implants that would be present *in vivo*. However, the calculated median static yield and runout moments applied during compression bending testing (calculated using the 40 mm moment arm) are 11.7 N-m and 7.8 N-m, respectively. These moments are more comparable with expected physiologic moments of 5–10 N-m in the thoracic and lumbar spine (Goel et al., 2006; Wilke et al., 1998). Because it is challenging to compare ASTM F1717 test results to expected physiological loads, it is more appropriate to compare mechanical performance between implants tested using the same methods. This study presents a robust collection of such data that can be utilized for comparative purposes.

Several clinically relevant failure modes are investigated using the ASTM tests for TPSSs. Reported *in vivo* mechanical failures of TPSSs include screw fracture, rod fracture, and dissociation of the screws from the rods (Bess et al., 2010; Jutte and Castelein, 2002; Lonstein et al., 1999). These mechanical failures also represent a large percentage of the adverse events submitted to FDA for TPSSs through Medical Device Reporting (MDR) (FDA, 2013). As shown in Table 4, screw and rod fracture are common failure modes during dynamic compression bending testing, indicating this test results in clinically relevant failure modes even if the measured forces are not physiologic. Conversely, 50% of static torsion tests resulted in screw rotation in the test blocks. This failure mode is not clinically relevant as the polymer test blocks used are intended to aid in testing repeatability but do not replicate the bone-screw interface. Therefore, testers should consider the validity of their test results based on the relevance of the failure mode(s) observed. Dissociation of screws from rods is not commonly observed during mechanical testing; however, user errors that are not simulated during mechanical testing, such as set screw cross–threading, may be partially responsible for this clinical failure mode. Another clinical failure mode commonly reported is screw loosening or pullout (Esses et al., 1993; Hicks et al., 2010). As described above, screw purchase is assessed in pullout testing per ASTM F543 using polyurethane foam as a surrogate for vertebral bone. Although polyurethane foam blocks used in testing of TPSSs typically have a uniform density that does not incorporate the regional bone density variations present in the pedicle and vertebral body, these methods do offer a repeatable methodology for assessment of screw purchase. Overall, the methods for testing TPSSs assess clinically relevant failure modes, but future work is warranted to assess the sensitivity of a TPSS to common variabilities introduced by different surgeons.

A surgeon's selection of the appropriate stiffness for a TPSS construct is multifactorial. Not surprisingly, in our dataset, ASTM F1717 construct compression bending stiffness was heavily driven by rod material and diameter as shown in Fig. 4. Construct stiffness increased as rod diameter increased, and for the 5.5 mm diameter, CoCr rods were the stiffer than Ti-Alloy and CP-Ti rods. These construct stiffness values aligned with those published by Stanford et al. for rods of the same diameter and material (Stanford et al., 2004). Because construct stiffness is correlated to rod material and diameter, rod selection can be an important decision in clinical outcomes (Yoshihara, 2013). A TPSS construct should provide sufficient stiffness to stabilize the spine for fusion. Large deformity corrections may require rods with greater stiffness in order to maintain the correction and provide adequate stability. However, higher stiffness TPSS constructs may stress shield an intended fusion site, overload the bone-screw interface, or lead to higher rates of sequelae at spinal levels adjacent to the implanted hardware such as proximal junctional kyphosis (Han et al., 2017; Mavrogenis et al., 2014). The most common rod observed in our dataset was 5.5 mm diameter, Ti-Alloy. This rod material and diameter combination likely results in adequate stiffness and sufficient strength for many scenarios. However, lower or higher stiffness constructs are likely desirable in certain circumstances, which is why many TPSSs offer a range of rod diameters and materials.

Table 3
ASTM F1798 and F543 mechanical test results.

	Component Type	Count	5th	25th	Percentile 50th	75th	95th	Coefficient of Variation (median [IQR])
Axial Gripping (Fz) Capacity (N)	Pedicle Screws	67	1067	1511	1791	2458	3873	0.079 [0.046, 0.114]
	Hooks	5	–	–	2013	–	–	0.095
	Lateral Connectors	17	1454	2218	2390	2575	3279	0.056 [0.043, 0.078]
	Rod-To-Rod Connectors	38	1181	2037	2592	3426	4444	0.092 [0.049, 0.120]
	Cross-Connectors	16	426	796	1112	1483	1604	0.121 [0.057, 0.141]
Torsional Gripping (Mz) Capacity (N-m)	Pedicle Screws	39	2.3	3.2	4.2	5.2	7.0	0.069 [0.046, 0.084]
	Hooks	5	–	–	4.1	–	–	0.112
	Lateral Connectors	14	3.5	3.7	4.8	5.8	7.5	0.042 [0.030, 0.066]
	Rod-To-Rod Connectors	31	1.6	5.5	6.6	8.2	10.8	0.075 [0.048, 0.129]
	Cross-Connectors	10	1.1	1.6	2.1	2.6	2.9	0.108 [0.101, 0.168]
Static Flexion-Extension (My) Yield Load (N)	Pedicle Screws	29	364	445	552	614	844	0.069 [0.038, 0.101]
Dynamic Flexion-Extension (My) Runout Load (N)	Pedicle Screws	12	194	260	293	320	334	–
Tulip Shank Dissocation (Fx) Max Load (N) - Neutral Angle	Pedicle Screws	34	4619	5687	6178	8329	9695	0.043 [0.017, 0.067]
Tulip Shank Dissociation (Fx) Max Load (N) - Max Angle	Pedicle Screws	25	4163	4938	5953	7450	8688	0.042 [0.019, 0.066]
Foam Block Pullout (Fx)[a] - Ultimate Pullout Load (N)	Pedicle Screws	15	291	383	444	496	591	0.027 [0.021, 0.047]

[a] Test results were only included for tests that utilized an insertion depth of 20 mm and Grade 15 foam.

Table 4
Distribution of failure modes observed for various mechanical tests[a].

	ASTM F1717			ASTM F1798					ASTM F543
Failure Mode	Static Compression Bending	Static Torsion	Dynamic Compression Bending	Axial Grip	Torsional Grip	Static F-E	Dynamic F-E	Tulip Shank Dissociation	Foam Block Pullout
Rod Failures									
Rod bending	19.7%	1.3%							
Rod fracture	2.7%	2.5%	57.4%[b]				5.9%		
Screw Failures									
Screw polyaxial mechanism angular slip	86.4%	58.8%	17.2%		8%	50.0%	17.6%		
Screw shank bending	4.8%	2.5%	2.3%			38.5%			
Screw shank fracture	4.8%	3.8%	60.9%			11.5%	64.7%	1.9%	
Screw tulip fracture							5.9%		
Set screw dislocation	0.7%								
Tulip dissociation from screw shank	0.7%	2.5%						98.1%	
Component Interconnection Failures									
Rotation of component about rod		20.0%	1.1%		92%				
Slippage/rotation of connector	2.7%	5.0%	2.3%						
Translation of component along rod				100%		11.5%	11.8%		
Other									
Pullout of screw from foam									100%
Screw rotation in test blocks		50.0%							

[a] Note that percentages often add up to over 100% because many tests report multiple failure modes.
[b] Rod fractures during dynamic testing occurred 82% near the screw head and 18% near a cross-connector or other type of connector.

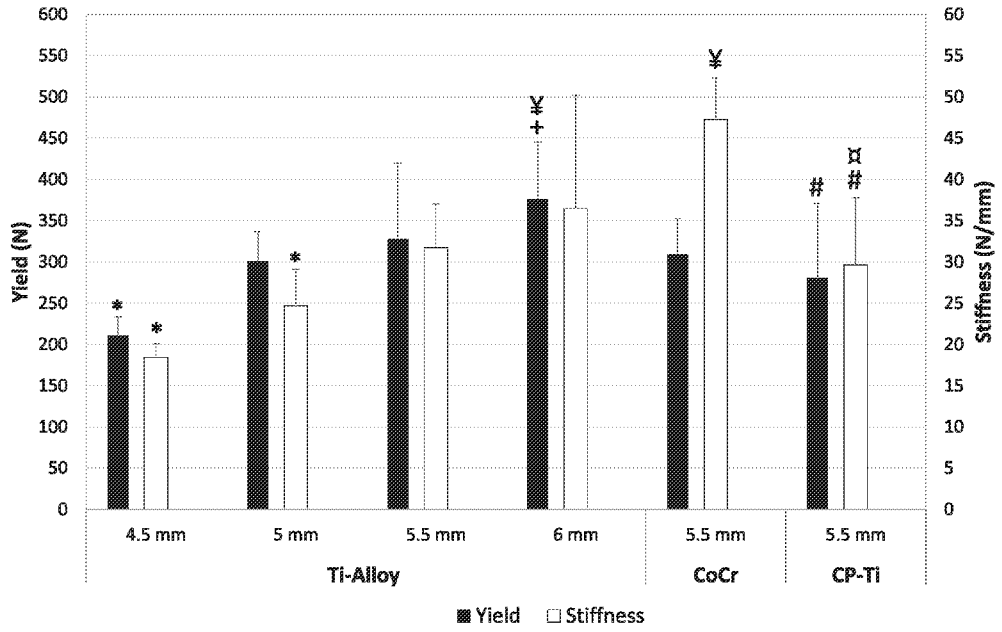

Fig. 4. Effect of rod diameter and rod material on ASTM F1717 static compression bending construct yield strength and stiffness. * indicates significant difference from all other rod configurations. + indicates significant difference from 5.0 mm Ti-Alloy. ¥ indicates significant difference from 5.5 mm Ti-Alloy. # indicates significant difference from 6.0 mm Ti-Alloy. ¤ indicates significant difference from 5.5 mm CoCr. $p < 0.05$ for all indicated comparisons.

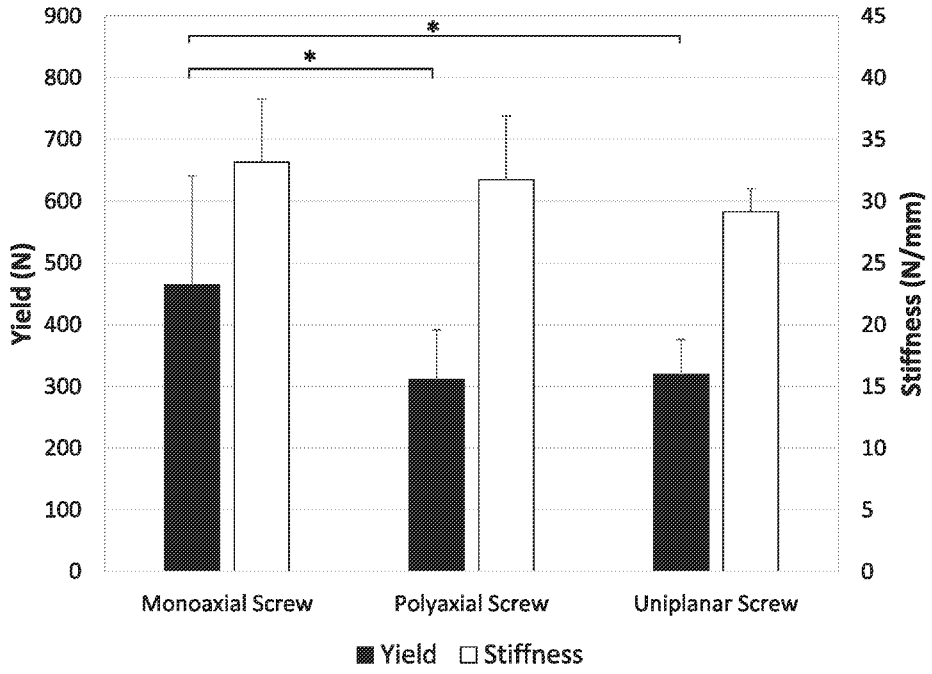

Fig. 5. Effect of screw type on ASTM F1717 static compression bending construct yield strength and stiffness. Depicted on the left axis, screw type has a significant effect ($p < 0.01$) on construct yield strength. Constructs with monoaxial screws had significantly higher yield than polyaxial and uniplanar screw constructs (*). Depicted on the right axis, construct stiffness was not affected by screw type ($p > 0.05$). To minimize a potential source of variability, this analysis was limited to tests that utilized 5.5 mm Ti-Alloy rods.

TPSSs often contain various screw types including polyaxial, uniplanar, and monoaxial. Polyaxial and uniplanar mechanisms offer important adaptability to the surgeon during surgery. Evaluation of these more complex mechanisms is important due to the potential for lower strength and/or different failure modes as compared to monoaxial screws. Constructs with polyaxial and uniplanar screws had lower ASTM F1717 compression bending yield strength than those with monoaxial screws (Fig. 5). During static compression bending tests, polyaxial and uniplanar screw constructs primarily failed via slippage of the polyaxial mechanism while monoaxial screw constructs primarily failed due to screw or rod bending. In high stress applications such as iliac fixation, surgeons may opt for larger diameter screws, but polyaxial mechanisms used in these screws typically require a smaller screw neck than a comparable diameter monoaxial screw. Therefore, the strength of the construct may be limited by failures of both the polyaxial mechanism itself and the smaller diameter screw neck. Polyaxial/uniplanar mechanisms can also fail by complete dissociation of the screw shank from the tulip. For this reason, manufacturers often evaluate the strength of the screw tulip-shank interface with dissociation testing (Table 3). Overall, the lower average static strength and additional potential failure modes associated with polyaxial and uniplanar screws as compared to monoaxial screws is likely offset by the undeniable surgical advantages these screws offer. However, the potential reduction in strength should be considered in high stress applications such as iliac fixation.

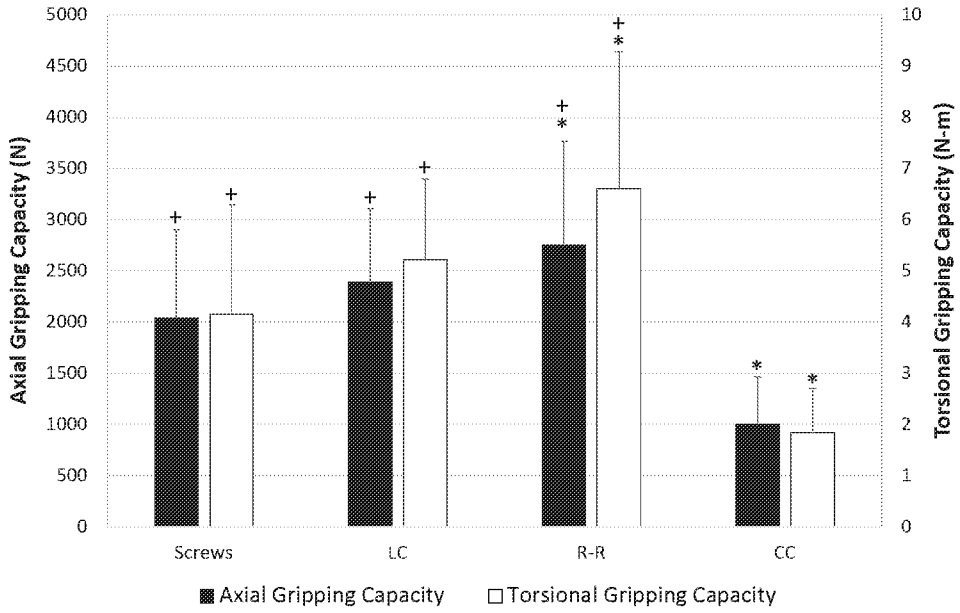

Fig. 6. Effect of component type on ASTM F1798 axial and torsional gripping capacity. Axial (left axis) and torsional (right axis) was evaluated from component testing of screws, lateral connectors (LC), rod-to-rod connectors (R-R), and cross connectors (CC). * indicates significant difference from screw gripping capacity. $^{+}$ indicates significant difference from CC gripping capacity.

Axial and torsional grip tests offer important assessments of the connection strength between the components and the rod. Axial and torsional gripping capacity was significantly weaker for CCs than all other component types. However, unlike the other component types, CCs are not designed to resist axial loads in the spine, and therefore may not need the interconnection strength of pedicle screws, hooks, R-Rs and LCs. Rather, CCs are utilized to provide torsional stability to constructs. Previous research has shown that CCs enhance the torsional stiffness of constructs, but as a tradeoff also may reduce the fatigue strength due to stress risers created by the attachment of the CCs to the rods (Serhan and Slivka, 2003). In the current dataset, 18% of rod failures during dynamic compression bending tests occurred directly adjacent to CCs or other connectors (Table 4). For this reason, FDA typically requests that CCs be included in dynamic compression bending testing to ensure the CC does not reduce construct fatigue strengths below acceptable levels.

One limitation of this study is that testing is typically conducted on worst case components and therefore the range of results do not represent the performance across the full range of components typically included in TPSSs. Furthermore, the overwhelming prevalence of certain components (e.g., 5.5 mm diameter Ti-Alloy rods, polyaxial screws) over other materials, dimensions, and component types limited the analyses that could be performed. Additionally, this study was limited to rigid TPSSs and inclusion of semi-rigid systems with lower stiffness was not possible due to the low number that have received FDA clearance to date. However, the current dataset may provide useful performance benchmarks for developers of these more novel systems.

In summary, this study presents a range of mechanical properties for the most commonly performed tests of TPSSs, which can be used during the development of future systems. Future work is planned to collect and analyze design and testing data on posterior cervical screw systems.

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Conflict of Interest Statement

The authors of this manuscript titled "Mechanical performance of thoracolumbosacral pedicle screw systems: An analysis of data submitted to the Food and Drug Administration" have no conflicts of interest to report. No external funding was received for this study.

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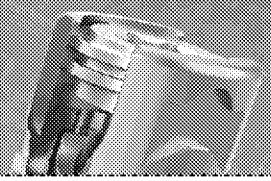

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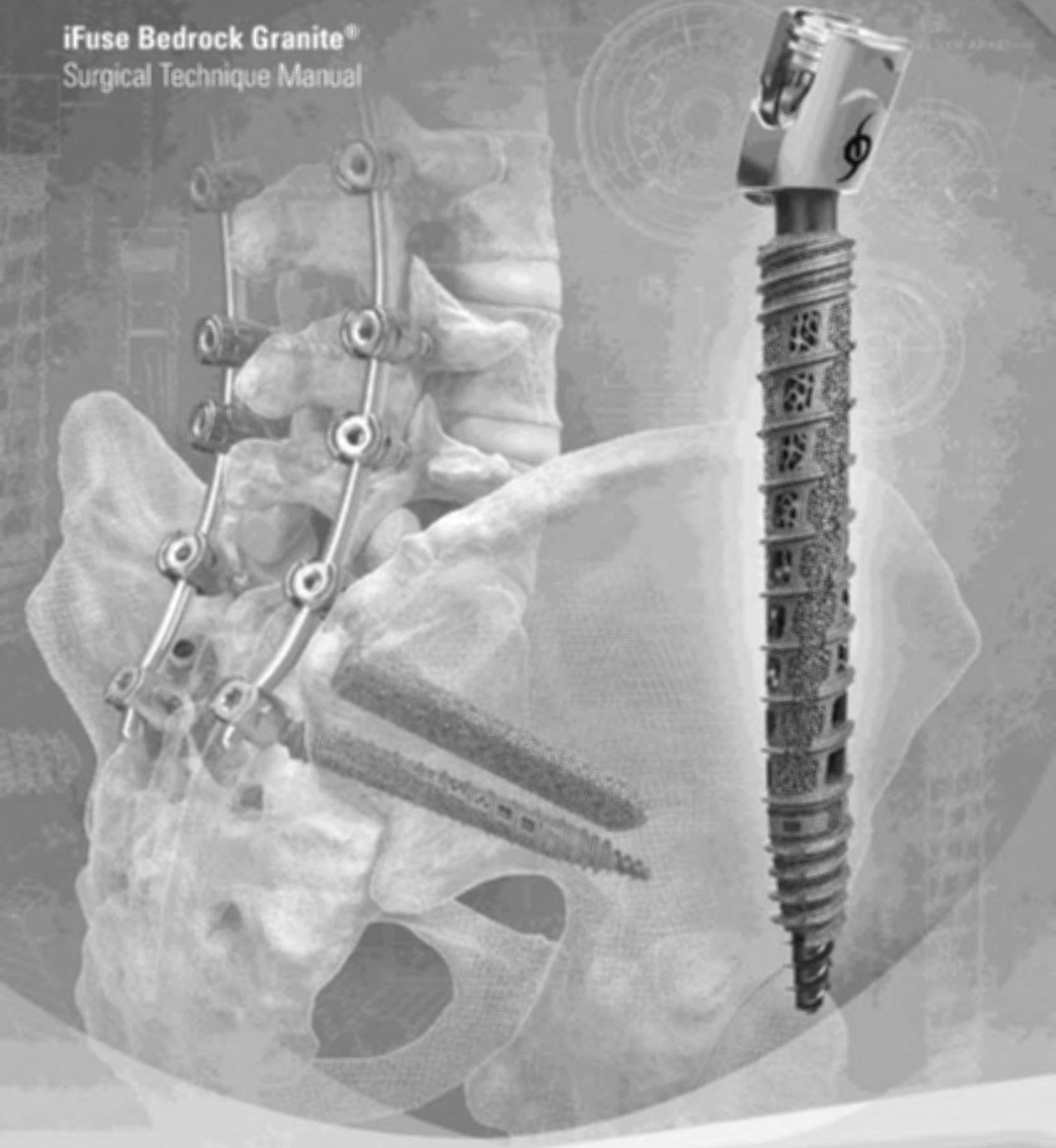


SI-BONE,
Sacropelvic Solutions™

Contents

About SI-BONE, Inc.

SI-BONE, Inc. is focused on the diagnosis and treatment of sacroiliac (SI) joint disorders. We are dedicated to educating surgeons on the diagnosis of lower back issues as they relate to the SI joint and training them to effectively perform surgeries with the goal of outstanding patient results every time.

iFuse Bedrock Granite® System: Introduction

The iFuse Bedrock Granite Implant System is intended to provide fusion of the sacroiliac joint and fixation to the pelvis when used with pedicle screw fixation as a foundational element for segmental spinal fusion. The procedure can be performed through an open surgical technique, or a minimally invasive surgical technique and implants are typically placed in a sacral-alar-iliac or iliac trajectory. Treatment with the iFuse Bedrock Granite Implant System was designed to minimize complications seen in multilevel long constructs (i.e., screw breakage, screw loosening, rod breakage, set screw failures) and address the stresses of the heavily loaded sacroiliac joint.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Bedrock Granite Implant System. Please review the Instructions For Use for a complete discussion of contraindications, warnings, precautions and risks.

iFuse Bedrock Granite® System Advantage

The iFuse Bedrock Granite System is intended for SI joint fusion and pelvic fixation.

ADVANTAGES:

- ***Intelliharvest Fenestrations*** *– Graduated fenestrations designed for optimal bone self-harvesting*
- ***FuSIon 3D Surface*** *– 3D-printed microporous lattice surfaces that mimic native cancellous bone for enhanced bone fixation*
- ***EZDrive Tip*** *– Tapered tip designed to reduce insertion force and offer more controlled Implant placement*
- ***OMNICapture System*** *– Designed to mitigate tulip splay, set screw disassociation, Implant neck fracture, and cross-threading while providing higher locking torque. Larger degree of tulip angulation for improved rod approximation*
- *Designed specifically for foundational fixation of multilevel long constructs and to fuse the heavily loaded SI joint*

Implant Part Numbers

Length (mm) Open Head Tulip	Diameter (mm) 9.5	10.5	11.5
40	095040BG	—	—
45	095045BG	—	—
50	095050BG	105050BG	—
60	095060BG	105060BG	—
70	095070BG	105070BG	115070BG
80	095080BG	105080BG	115080BG
90	095090BG	105090BG	115090BG
100	095100BG	105100BG	115100BG
110	095110BG	105110BG	—
120	095120BG	105120BG	—

Length (mm) Closed Head Tulip			
40	095040CH	—	—
45	095045CH	—	—
50	095050CH	105050CH	—
60	095060CH	105060CH	—
70	095070CH	105070CH	115070CH
80	095080CH	105080CH	115080CH
90	095090CH	105090CH	115090CH
100	095100CH	105100CH	115100CH
110	095110CH	105110CH	—
120	095120CH	105120CH	—

Description	Standard Part No.
Set Screw	501117

Pre-Op Planning and Patient Set-Up

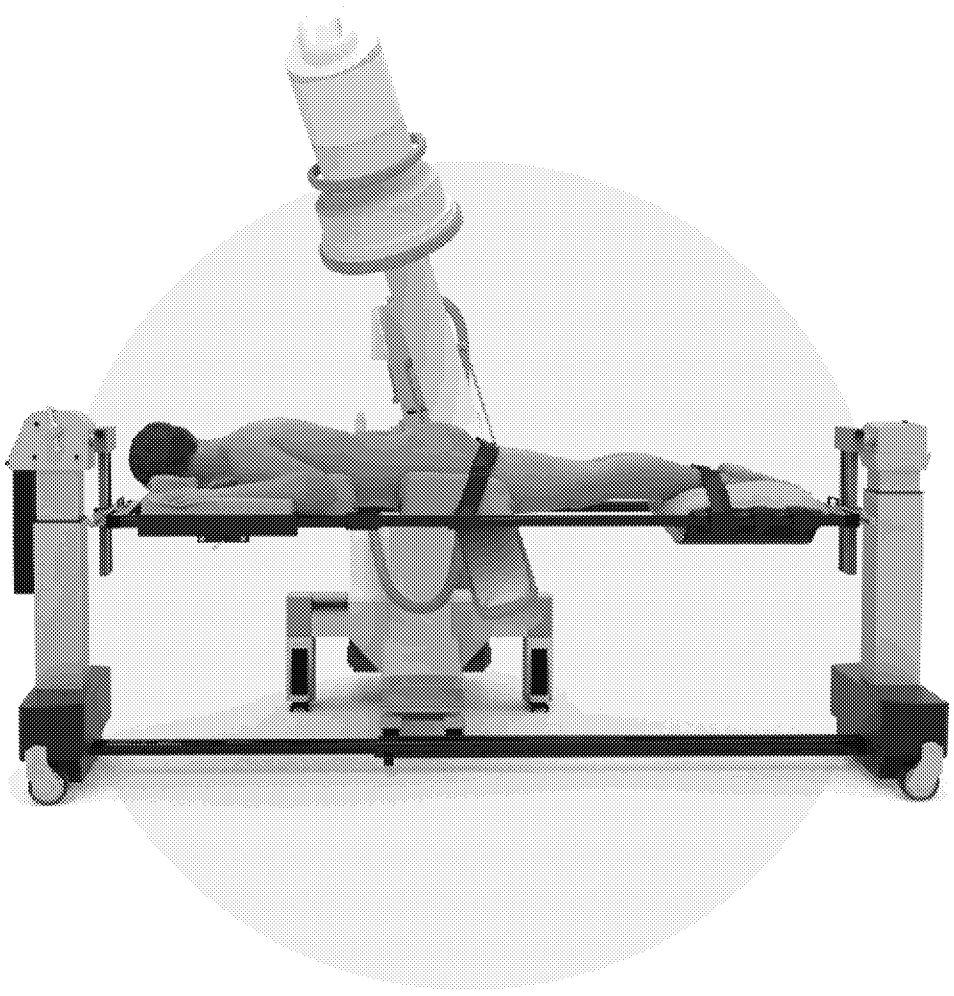
Pre-Op Planning

- A CT is recommended for pre-op planning.
  - » Check for anatomic abnormalities
- Ensure compatibility of all planned implanted components. This may involve contacting your SI-BONE representative or the pedicle screw manufacturer with any questions or concerns to ensure compatibility of all implanted components.

Patient Positioning:

- This procedure may be performed in standard prone positioning for deformity surgery.

***NOTE**: This manual is provided for reference only. The procedure should be adjusted based on patient characteristics and the surgeon's judgment. Instruments not shown in this manual may be used at the surgeon's discretion.*



- Utilize anterior-posterior (AP) view of the pelvis (or outlet view) for approximation of the sciatic notch. Instrument/Implant path should be just cephalad (within 20mm) of the sciatic notch when aiming toward the (anterior inferior iliac spine) AIIS.
- Utilize an inlet view to confirm trajectory has not violated the ventral cortex of the pelvis.
- Utilize the teardrop view to confirm the anterior posterior trajectory is within the confines of the iliac tables. Obturator oblique with a 30° caudal and 30° lateral beam. Reference **Figs. 1-4** for C-arm set up and approximate fluoroscopic result.

Figure 1

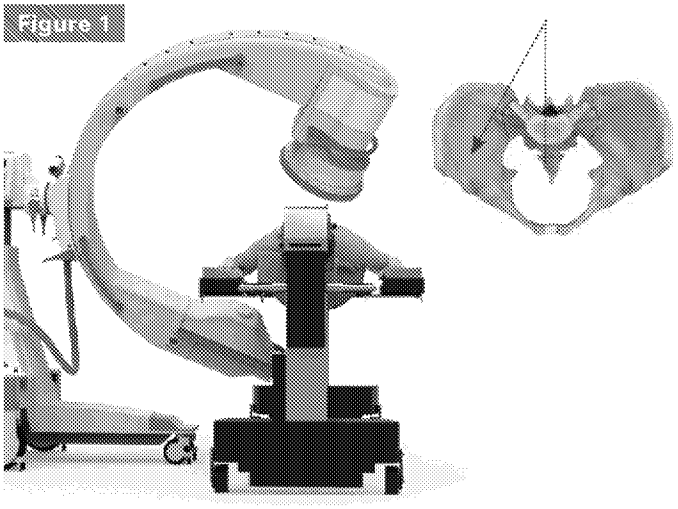


Figure 2

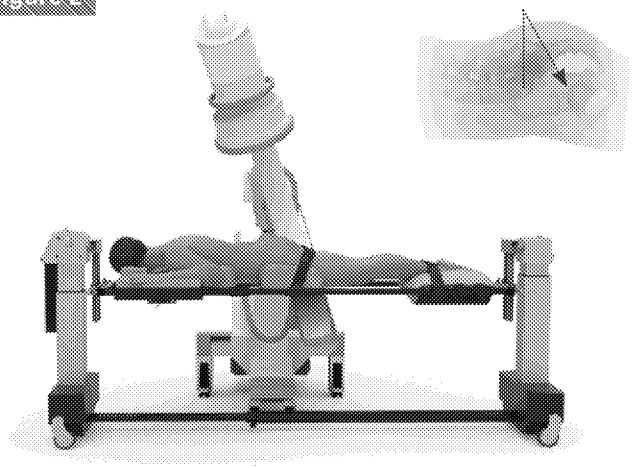
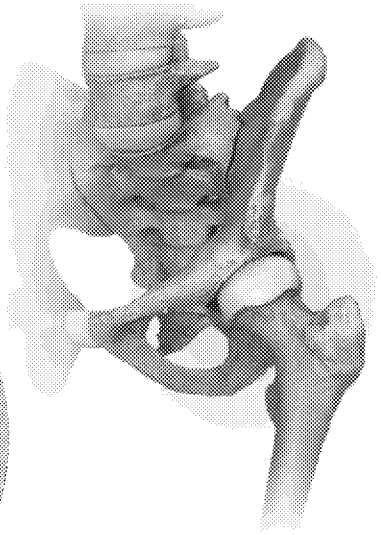


Figure 3



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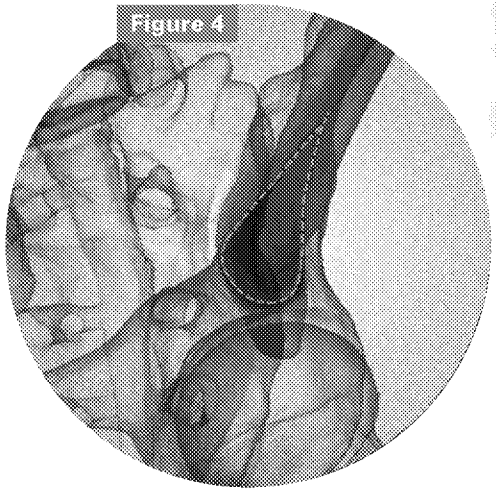
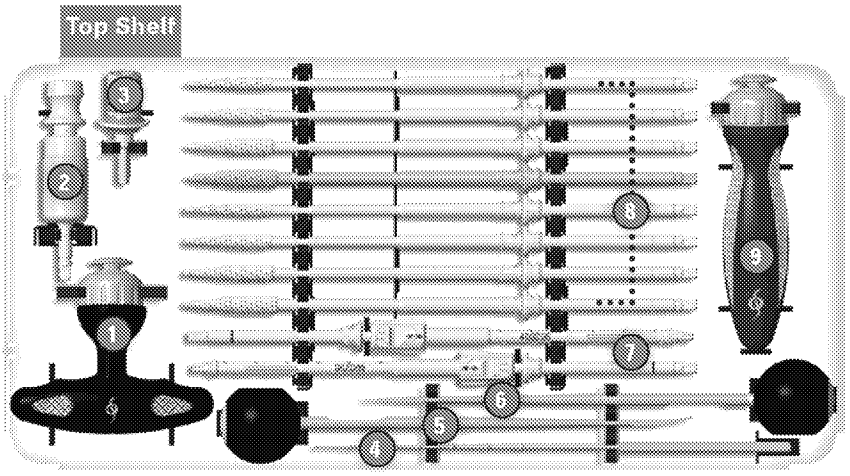
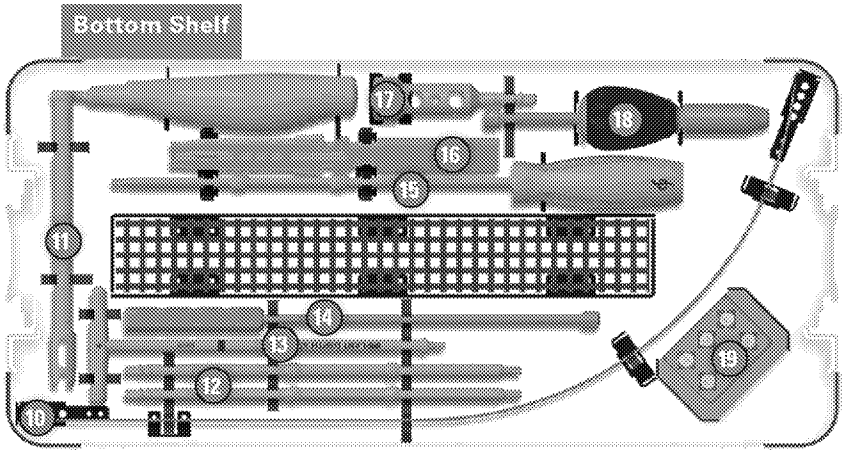
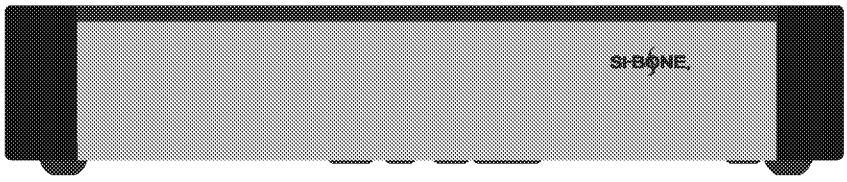


Open Procedure: Instrument Tray Layout

1. T-Handle, Ratcheting, Quarter Square, Low Profile
2. Torque Limiting Adapter 115 in-lb
3. QC Adapter, Quarter Inch to Trilobe
4. Bedrock Granite Measurement Probe
5. Bone Probe, Curved
6. Bone Probe, Straight
7. Navigation, Locking Driver
8. Taps (Cannulated and Awl Tip)
9. Inline Handle, Ratcheting, Quarter Square, Low Profile
10. Bedrock Granite Guidewire Sharp (1.4mm) – *Disposable item*
11. Counter Torque
12. T30 Final Driver
13. Implant Depth Adjuster
14. Head Turner
15. Set Screw Starter, Axial
16. Axial Reducer
17. Bedrock Granite Threaded Reducer Extension
18. Guidewire Driver
19. Set Screw Caddy





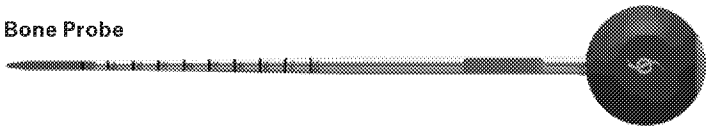


Open Procedure: Pilot Hole Preparation

- Prepare a pilot hole for the Implant using the Bone Probe, typically at the midpoint between the S1 and S2 dorsal foramen and in line with the lateral border of the foramen **(Fig. 5).**
- Advance the Bone Probe toward the patient's anterior inferior iliac spine, which can be found by palpating the top of the greater trochanter **(Fig. 6).**
- Advance the Bone Probe to terminal depth **(Fig 7).** Depth markings are available for Implant measurement.
- Use fluoroscopy to confirm trajectory as the instrument advances.

NOTE: *The gold, box tip length of the Bone Probe is 30 mm, with depth markings from 30 mm to 120 mm, marked in 10 mm increments.*

PRECAUTION: *The Bone Probe tip is sharp and can puncture or tear gloves.*



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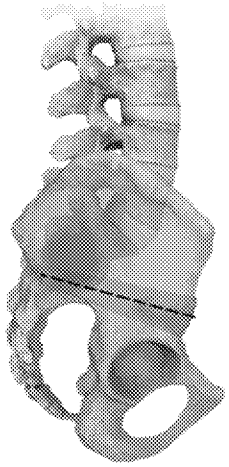


Figure 6

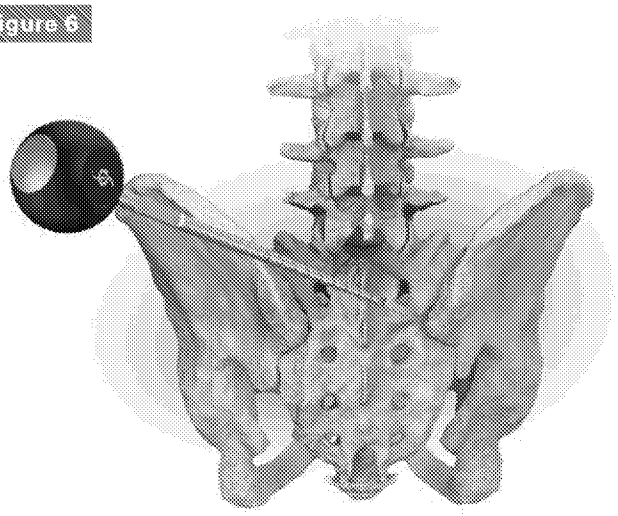
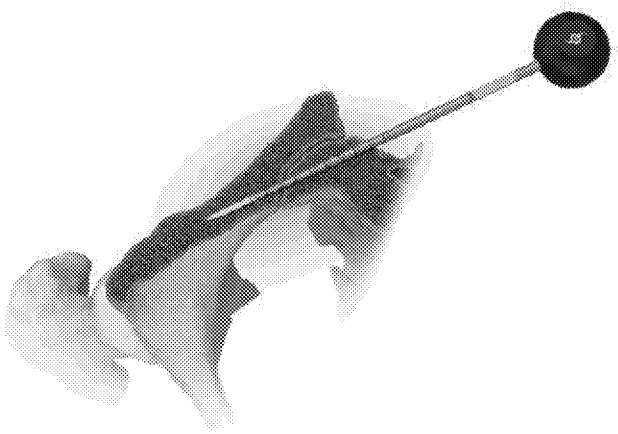


Figure 7



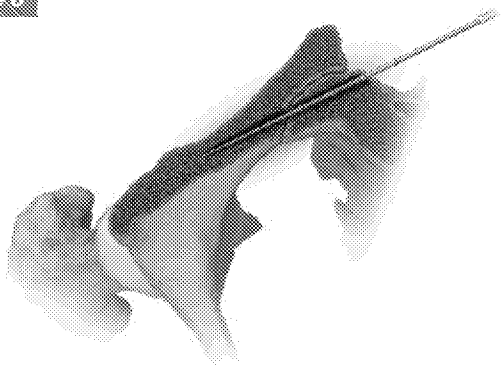
Open Procedure: Pilot Hole Verification

- Advance the Measurement Probe into the pilot hole to confirm the integrity of the inner and outer cortical walls of the ilium and measure desired Implant length **(Fig. 8).**
- Determine the desired Implant length by counting the number of nodes on the Measurement Probe **(Fig. 9).**

NOTE:

- *The nodes are spaced apart in 20 mm increments from 20-120 mm.*
- *The depth of Implant engagement within the sacrum and the ilium may be visualized using the Measurement Probe in an outlet oblique view **(Fig. 10, 11).***
- *A standard ball-tip feeler probe may also be used to confirm pilot hole integrity.*
- *A surgical clamp may be used on the Measurement Probe or the standard ball-tip feeler probe at the dorsal sacrum to confirm depth measurement by counting the nodes on the Measurement Probe or measuring the ball-tip feeler.*

Figure 8



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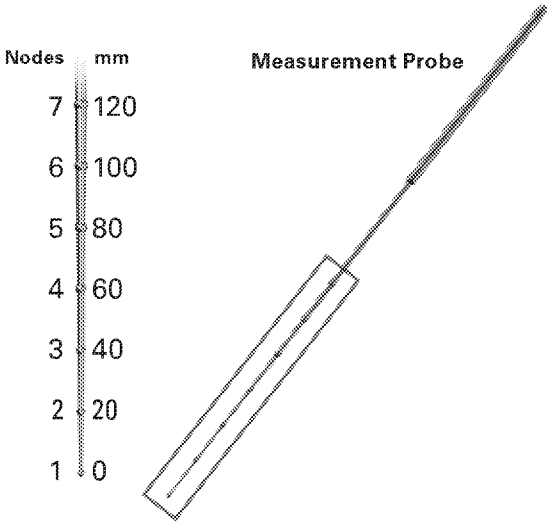

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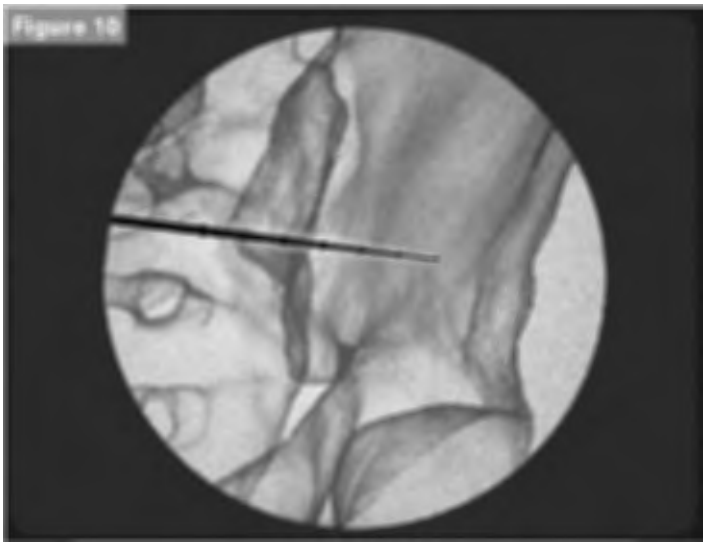
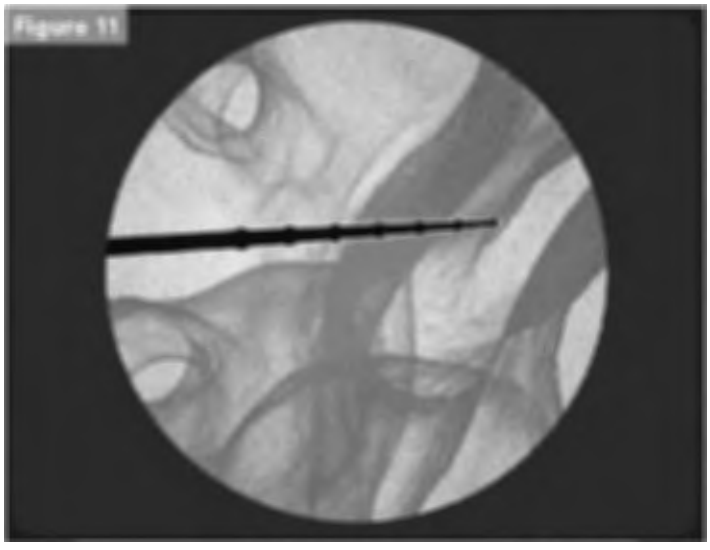


Figure 11



Open Procedure: Tapping

- Solid Awl Tip Taps and Cannulated Taps for use over a Guidewire are provided.
- Sequentially tap to desired Implant length and diameter **(Fig. 12)** using the depth markings for reference (60 mm – 120 mm in 10 mm increments).

NOTE**: Some users may elect to undersize with taps based on bone quality **(Table, Fig. 13).

- Confirm tap depth and placement as the instrument advances under fluoroscopic visualization.

NOTE:

- *Taps are true to size (i.e. the 10.5 mm Tap has a 10.5 mm major diameter).*
- *The black ring on the proximal shaft of the Tap will not be visible when the handles or the optional Quick Connect (QC) Adapter are properly engaged **(Fig. 14).***
- *All Taps have depth markings from 60 mm to 120 mm, in 10 mm increments.*
- *A QC Adapter (1/4" square to Tri-lobe) for use with power is provided.*

Solid Awl Tip Tap

Figure 12

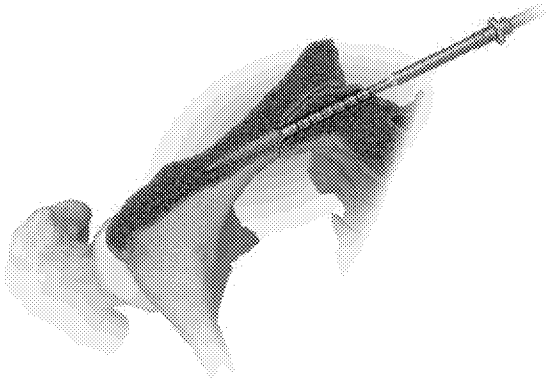


Figure 13

Implant Size (mm)	Undersized	Line-to-Line
10.5	8.5, 9.5	10.5
11.5	8.5, 9.5, 10.5	11.5

Additional tap sizes are available upon request

Figure 14

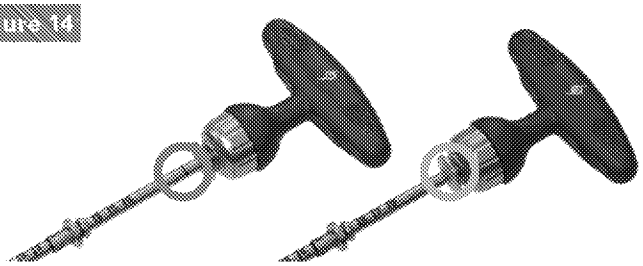
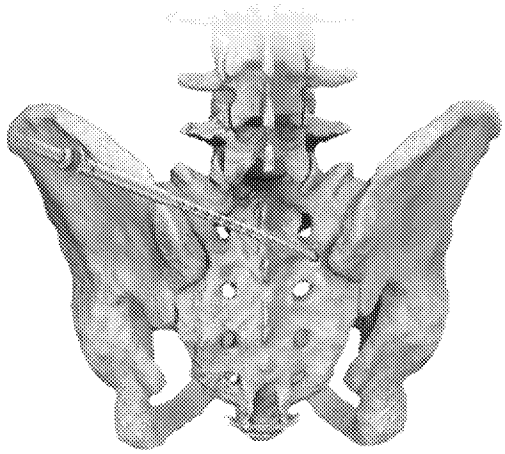


Figure 15



Open Procedure: Transferring the Implant to the Sterile Field

Circulator

- Remove the outer polywrap of the Implant tube and remove labels.

> ***NOTE**: Implant sizing may be referenced on both the cap and the tube.*

- Hold the Implant tube vertically in one hand with the cap up. Unscrew and remove the cap counterclockwise, breaking the seal **(Fig. 16).**

> ***NOTE**: Once Implant tube cap is removed, do not touch the sterile threaded portion of the Implant tube or the sterile clamshell **(Fig. 17).***

- Aseptically transfer the contents of tube (clamshell containing Implant) to the sterile field.
  - » OPTION 1: Hand-to-hand transfer
  - » OPTION 2: Drop transfer to sterile basin

Figure 16

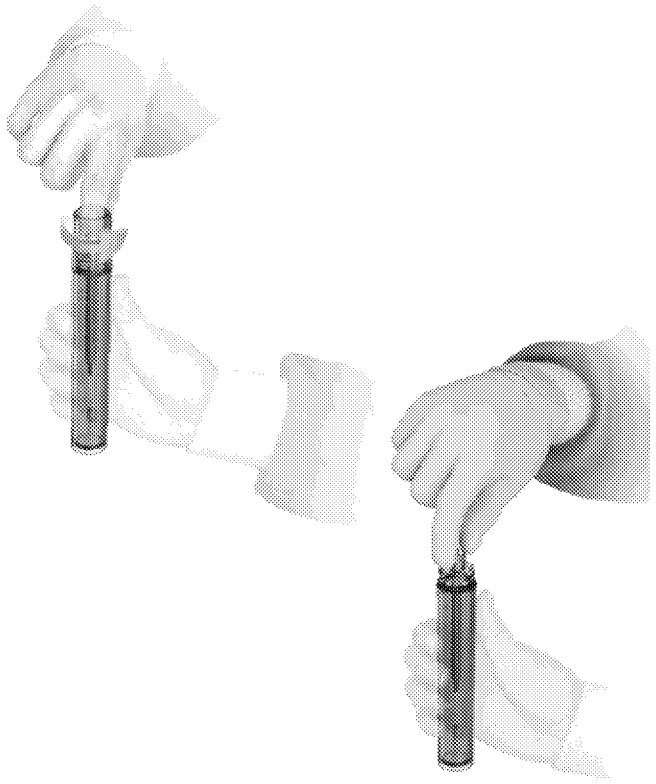
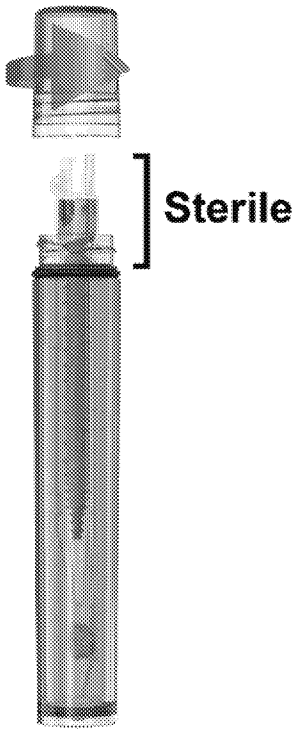
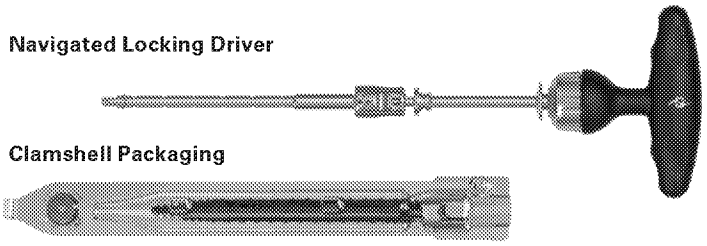


Figure 17



Back Table Assist (sterile)

- Hold the sterile clamshell packaging vertically. Pinch the tulip and neck through the clamshell to prevent tulip rotation **(Fig. 18).**
- Insert the hexalobe tip of the Navigated Locking Driver into the hexalobe drive feature of the screw **(Fig. 19).**
- Maintaining the Implant in a vertical position, advance the outer sleeve of driver into tulip. Rotate the outer sleeve clockwise until it is fully engaged into tulip threads **(Fig. 20).**
- Slide the gold locking button distally toward the Implant into the locked position **(Fig. 21).**
- With a secure hold on the sterile clamshell, remove the loaded Implant assembly by pulling up on the Navigated Locking Driver **(Fig. 22)**.
- Keep the sterile clamshell which contains the Implant set screw.



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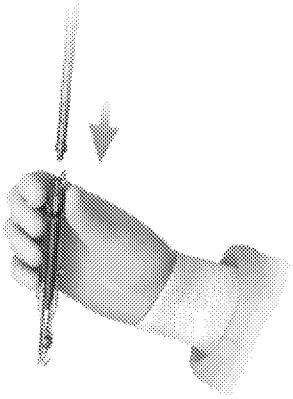


Figure 19

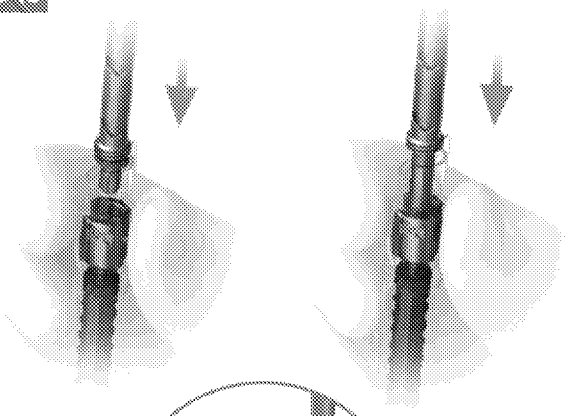


Figure 20

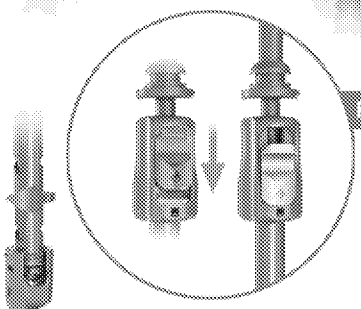


Figure 21

Figure 22

Open Procedure: Implant Placement

- Attach desired handle to the proximal end of the Navigated Locking Driver and advance the Implant assembly to desired depth using fluoroscopy **(Fig. 23).**

***NOTE**: The black ring on the proximal shaft of the Navigated Locking Driver will not be visible when the handles or the optional Quick Connect (QC) Adapter are properly engaged.*

- Slide the gold locking button proximally, away from Implant into the unlocked position.
- Unthread the outer sleeve of the Navigated Locking Driver from the tulip threads by rotating counterclockwise **(Fig. 24).**
- Remove the Navigated Locking Driver from placed Implant.

***NOTE**:*

- *A Head Turner is available to rotate Open Head Implant tulips clockwise to optimize the favored angle. Do not rotate the tulip counterclockwise. Rotating counterclockwise may unthread the tulip head from the Implant body.*
- *A Depth Adjuster with Wings is available for use with Open Head Implants to make additional adjustment to implant depth.* ***This instrument is not compatible with Closed Head Implants.***
- *To adjust the favored angle tulip on a Closed Head Implant, a standard needle nose driver (not included in the instrument tray) can be used to rotate the tulip clockwise to optimize the favored angle. Grip the tulip head at the non-threaded bridge portion when adjusting.*

Figure 23

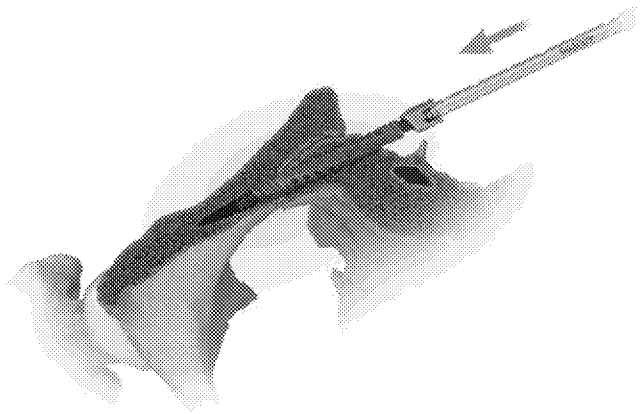
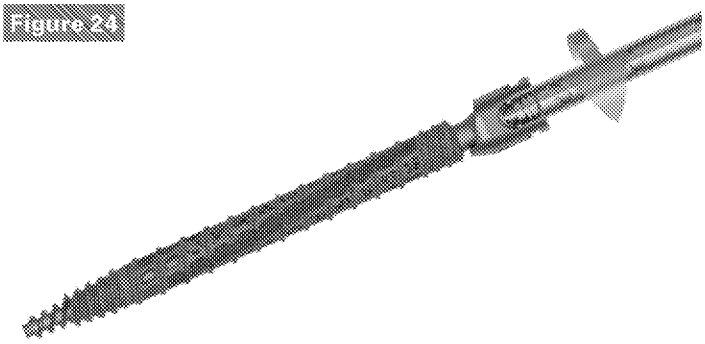


Figure 24



PRECAUTIONS:

- *As the Implant advances, the sacroiliac joint cortices may deflect the Implant anteriorly. Use either inlet or teardrop fluoroscopy to confirm desired trajectory is maintained.*
- *Instrument and Implant tips have potential to puncture or tear gloves.*
- *Avoid damaging the tulip head threads when manipulating the Closed Head Implant tulip using a needle nose driver. Damage may cause set screw to not properly engage.*

Open Procedure: Rod Reduction & Set Screw Placement

- Retract the inner sleeve of the Axial Reducer by rotating the knurled knob counterclockwise. Secure the distal attachment feature of the Axial Reducer onto the tulip head until full engagement can be confirmed.
- Turn the knurled knob of the Axial Reducer clockwise to advance the inner sleeve until the rod is fully reduced and seated into the bottom of the tulip head **(Fig. 25).**
- Alignment of the black and silver laser mark indicates when the rod is fully seated and reduction is complete.
- Retain the set screw onto the Set Screw Starter by aligning the distal star tip of the Set Screw Starter to the set screw and pushing down firmly. The Set Screw Starter will self-retain the set screw. **(Fig. 26)**
- Insert the Set Screw Starter with set screw attached through the center of the Axial Reducer. Tighten until "two-finger tight."
- Remove the Set Screw Starter by pulling up.

NOTE:

- *There are six additional set screws found within the Set Screw Caddy in the instrument tray, should the set screw from the original Implant packaging be compromised.* ***(Fig. 27)***
- *Facilitate the set screw engagement by rotating the Set Screw Starter counter-clockwise, then clockwise to properly engage the threads. This will mitigate cross-threading.*

- To disengage the Axial Reducer, depress both side buttons and detach from the tulip head.

Figure 25

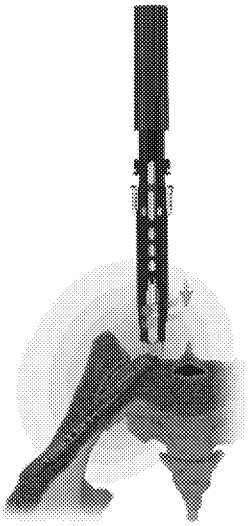


Figure 26

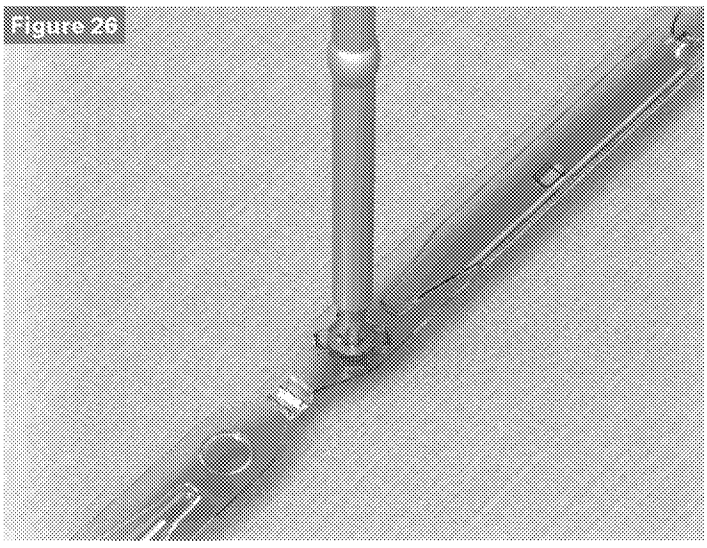
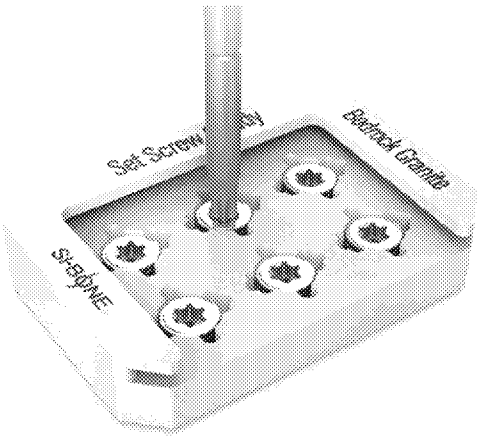


Figure 27

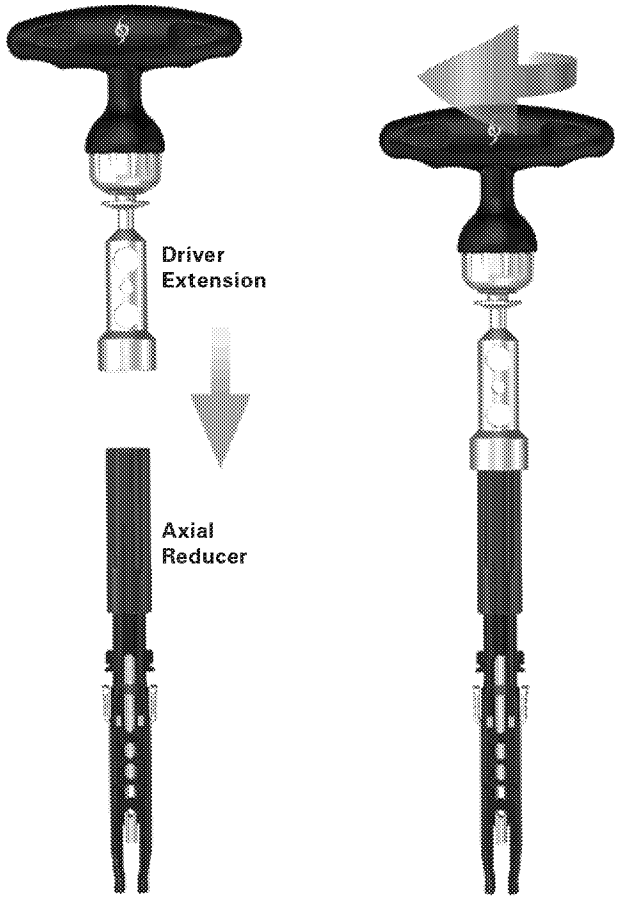


Open Procedure: Rod Reduction & Set Screw Placement

OPTIONAL: Use the Threaded Reducer Extension in conjunction with a modular handle to apply additional torque during rod reduction **(Fig. 28).**

- This assembly requires the preferred modular handle, Reducer Driver Extension, and Axial Reducer.

Figure 28



Open Procedure: Final Tightening

- Assemble the T30 Final Driver **(Fig 29 b)** to the Torque Limiting Adapter **(Fig 29 c),** and to the T-Handle **(Fig 29 d).** Slide the distal end of the T30 Final Driver through Counter Torque **(Fig 29 a)** and into the set screw head. Slide the Counter Torque down, fully seating it over the Implant tulip and rod **(Fig. 30).**
- Final tighten the set screw by turning the T-Handle clockwise until a minimum of two audible clicks are heard or tangibly felt.

***NOTE**: The iFuse Bedrock Granite System requires final tightening to 115 in-lb (13 Nm).*

ALWAYS use the Torque Limiting Adapter together with the Counter Torque to prevent disruption of the construct.

Final Driver Assembly

Figure 29 a

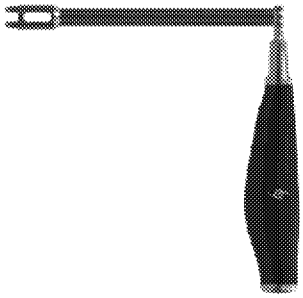


Figure 29 b

Figure 29 c

Figure 29 d

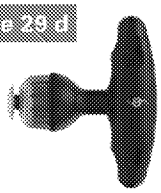
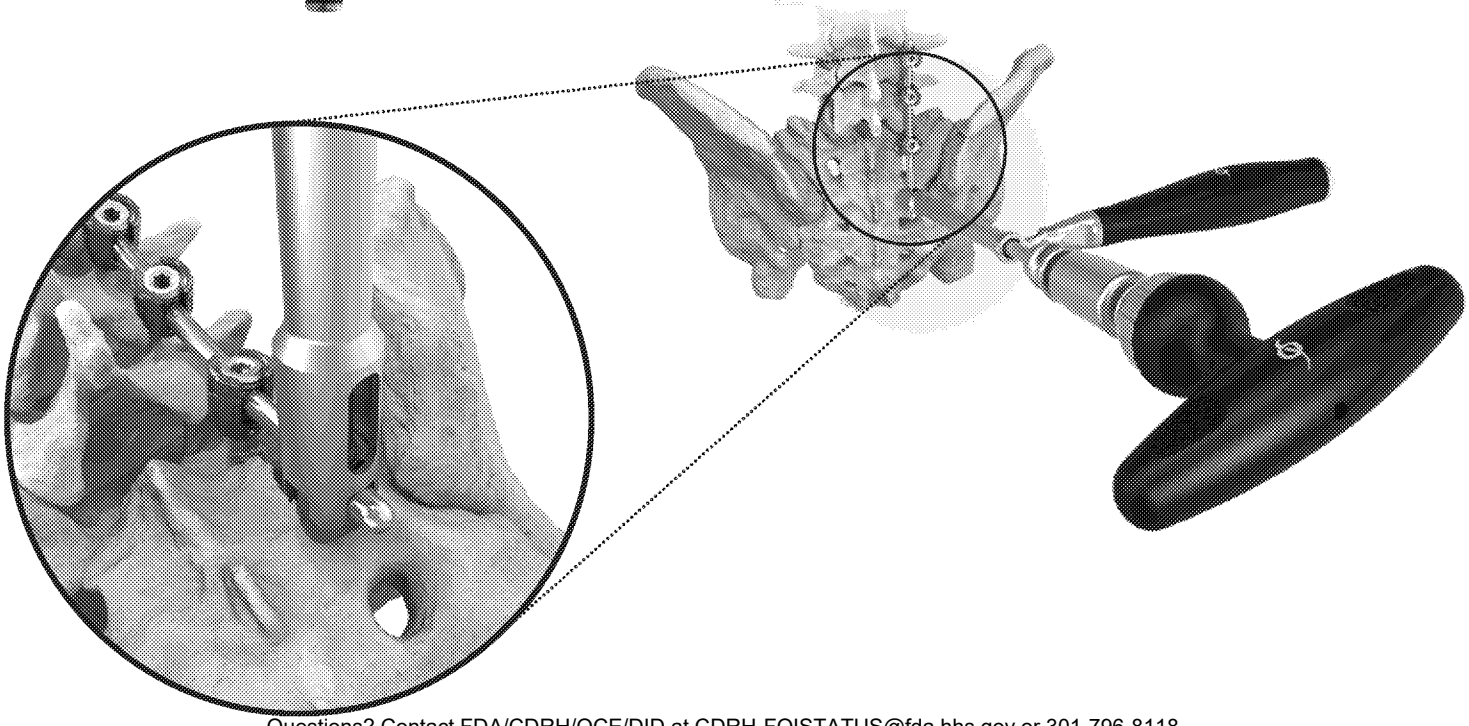


Figure 30



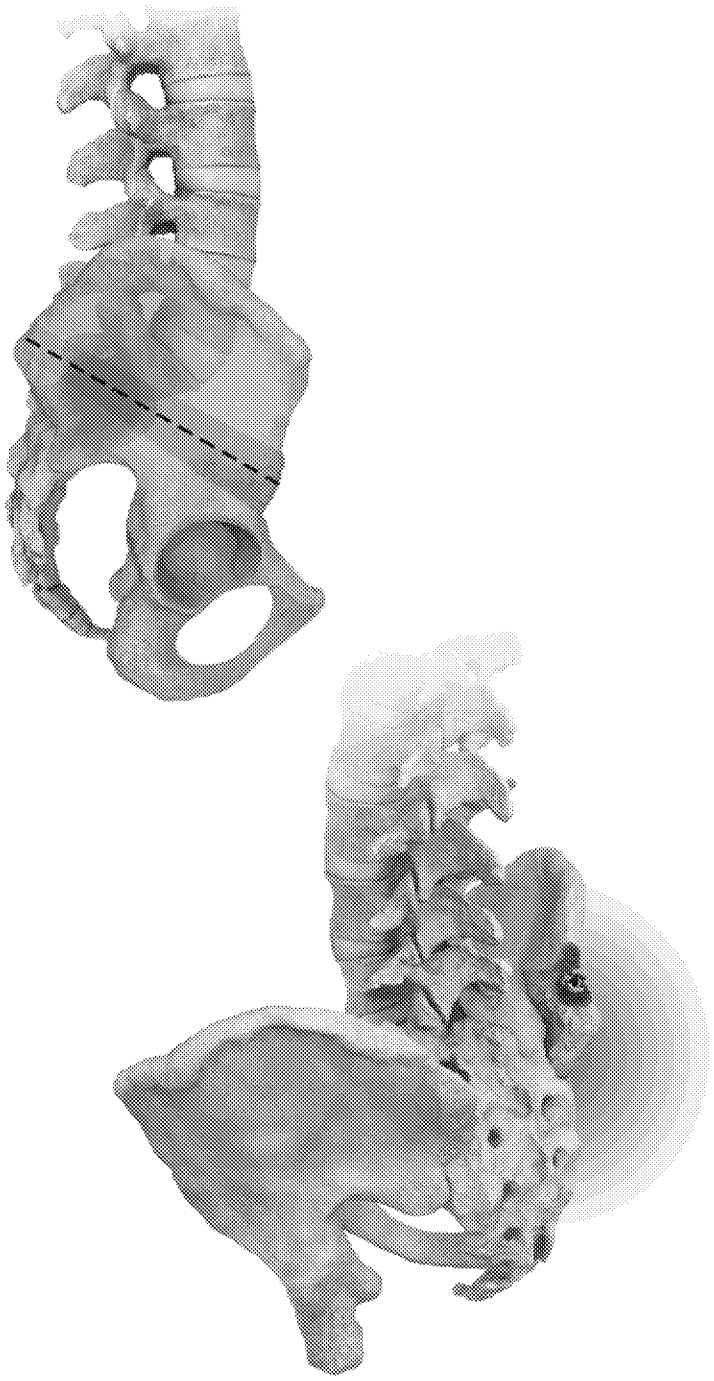
Procedure: Iliac Placement (Optional)

- One or more Granite Implants may be placed in an iliac trajectory using standard techniques and the same instrument sequence as S2AI placement.

***NOTE**: The iFuse Bedrock Granite Implant System does not include transverse connectors or rods..*

- The iliac trajectory is highly variable, but typically is angled approximately 20–45 degrees caudal and 30–45 degrees lateral. In selected cases, placement of two Granite Implants per ilium can be performed as well. In these cases, careful planning of the first Implant will make placement of the second Implant easier, as the more caudal Implant should be placed low within the ilium 'tear drop' and immediately above the sciatic notch. This will allow adequate room for the second Implant within the remainder of the cephalad ilium.

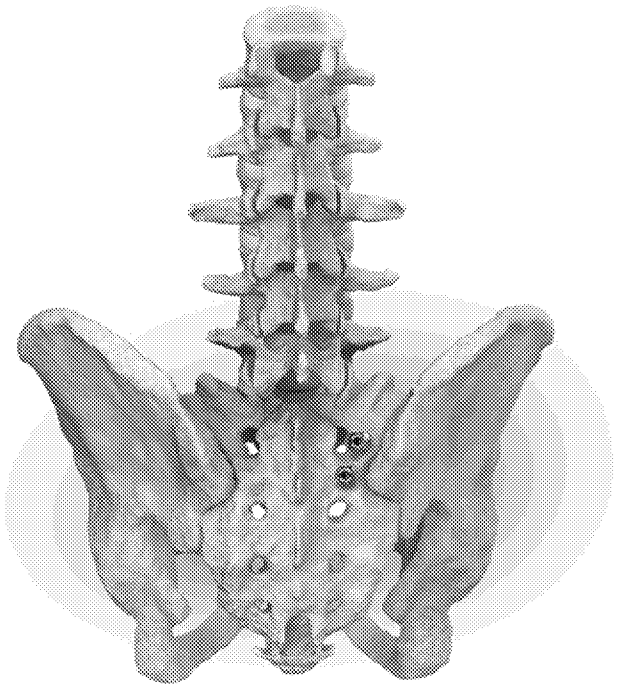
Figure 31



Procedure: Stacked Granite Placement (Optional)

- A second Granite Implant may be placed in conjunction with an S2AI-trajectory Granite Implant. The second, cephalad Implant starting point is typically midway between the S1 pedicle screw and S2AI Implant. Frequently placed at the lateral border of the S1 neuroforamen. In these selected cases, careful planning of the first Implant will make placement of the second Implant easier.
- The trajectory of the Implant path runs in a caudal and lateral direction through the ala and into the ilium, towards the ASIS. The surgeon should direct the Implant 40°–50° laterally in the transverse plane, similar to S2AI screws.

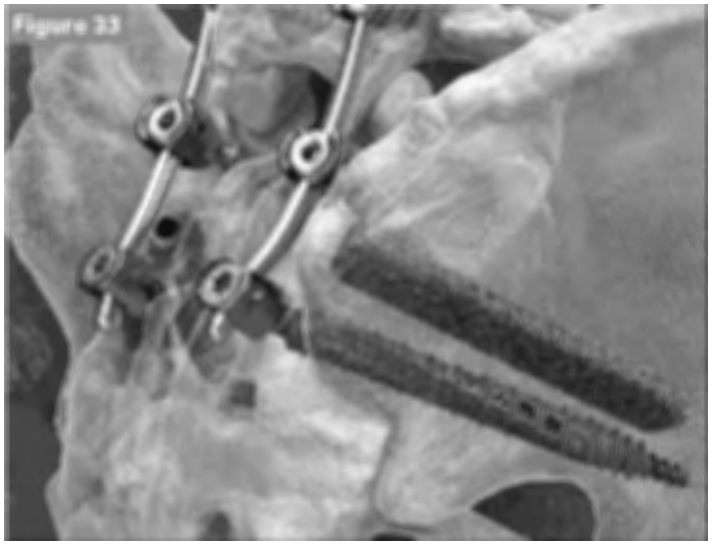
Figure 32



NOTE: *If SI joint fusion is desired, iFuse Bedrock Granite should be placed across the SI Joint in the sacral alar iliac trajectory along with a second sacroiliac fusion promoting device placed across the joint.*

Procedure: iFuse Bedrock + Granite (Optional)

- A secondary iFuse Implant may be used in conjunction with a Granite Implant using standard techniques and the same instrument sequence as S2AI placement.
- The second, cephalad iFuse Implant starting point is typically midway between the S1 pedicle screw and S2AI Implant. Frequently placed at the lateral border of the S1 neuroforamen. In these selected cases, careful planning of the first Implant will make placement of the second Implant easier.



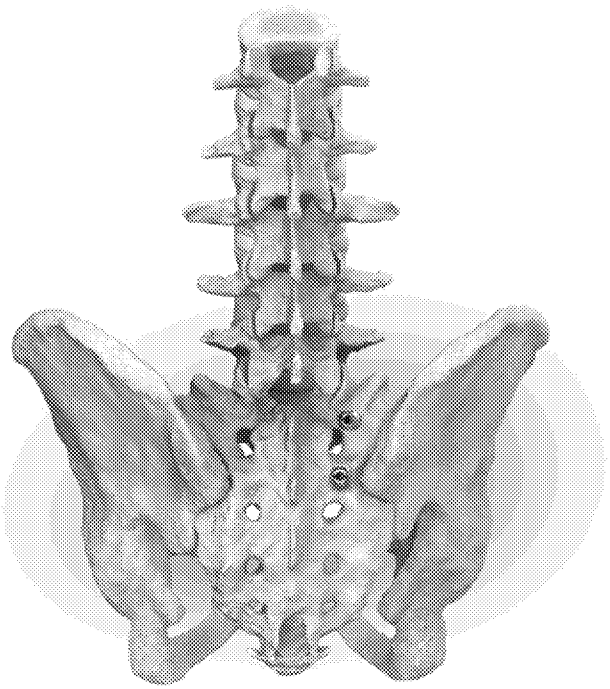
NOTE: *If SI joint fusion is desired, iFuse Bedrock Granite should be placed across the SI Joint in the sacral alar iliac trajectory along with a second sacroiliac fusion promoting device placed across the joint.*

Procedure: S1AI Placement (Optional)

- A second Granite Implant may be placed in conjunction with an S2AI-trajectory Granite Implant, in an S1AI trajectory. Placement will use standard techniques and the same instrument sequence as S2AI placement. The S1AI trajectory is highly variable, but typically starts just lateral to the junction of the S1 superior articular facet and the posterior sacral ala. It is typically 3-5mm above the superolateral corner of the S1 foramen. In these selected cases, careful planning of the first Implant will make placement of the second Implant easier.
- The trajectory of the Implant path runs in a caudal and lateral direction through the sacral ala and into the ilium. The surgeon should direct the more cephalad Implant 40°–50° laterally in the transverse plane, similar to S2AI screws.

NOTE: *If SI joint fusion is desired, iFuse Bedrock Granite should be placed across the SI Joint in the sacral alar iliac trajectory along with a second sacroiliac fusion promoting device placed across the joint.*

Figure 34



Procedure: S1 Pedicle Placement (Optional)

- The iFuse Bedrock Granite Implant may be placed in the S1 pedicle trajectory. The S1 trajectory is highly variable, but typically starts 5-10mm caudal and 10mm lateral to the junction of the S1 superior articular process of S1. Ensure that the starting point for S1 placement does not interfere with the placement of other Implants or preclude attachment of the Implant to the rod.
- Use standard imaging techniques to determine Implant starting position and trajectory. Device implantation should follow the same sequence as described for S2AI placement

Figure 35

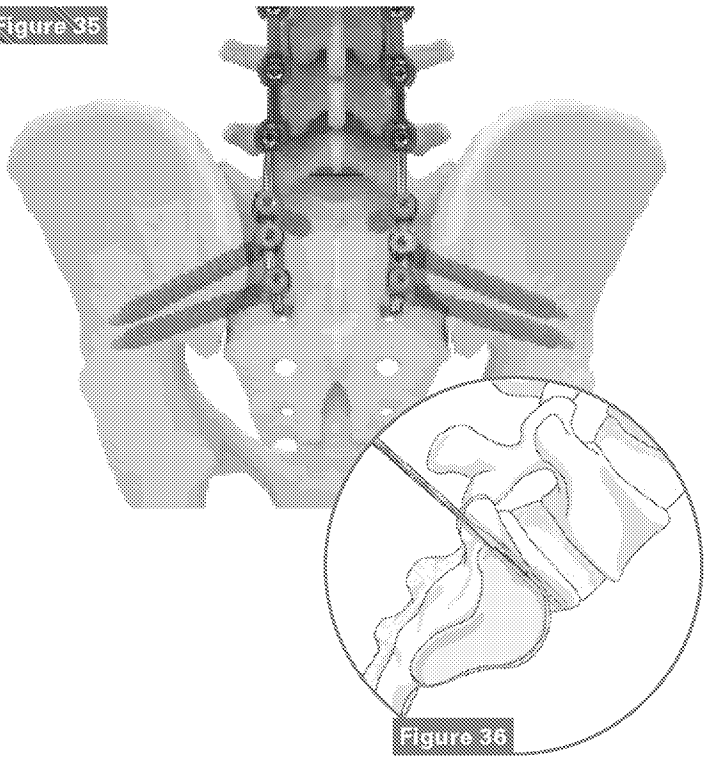
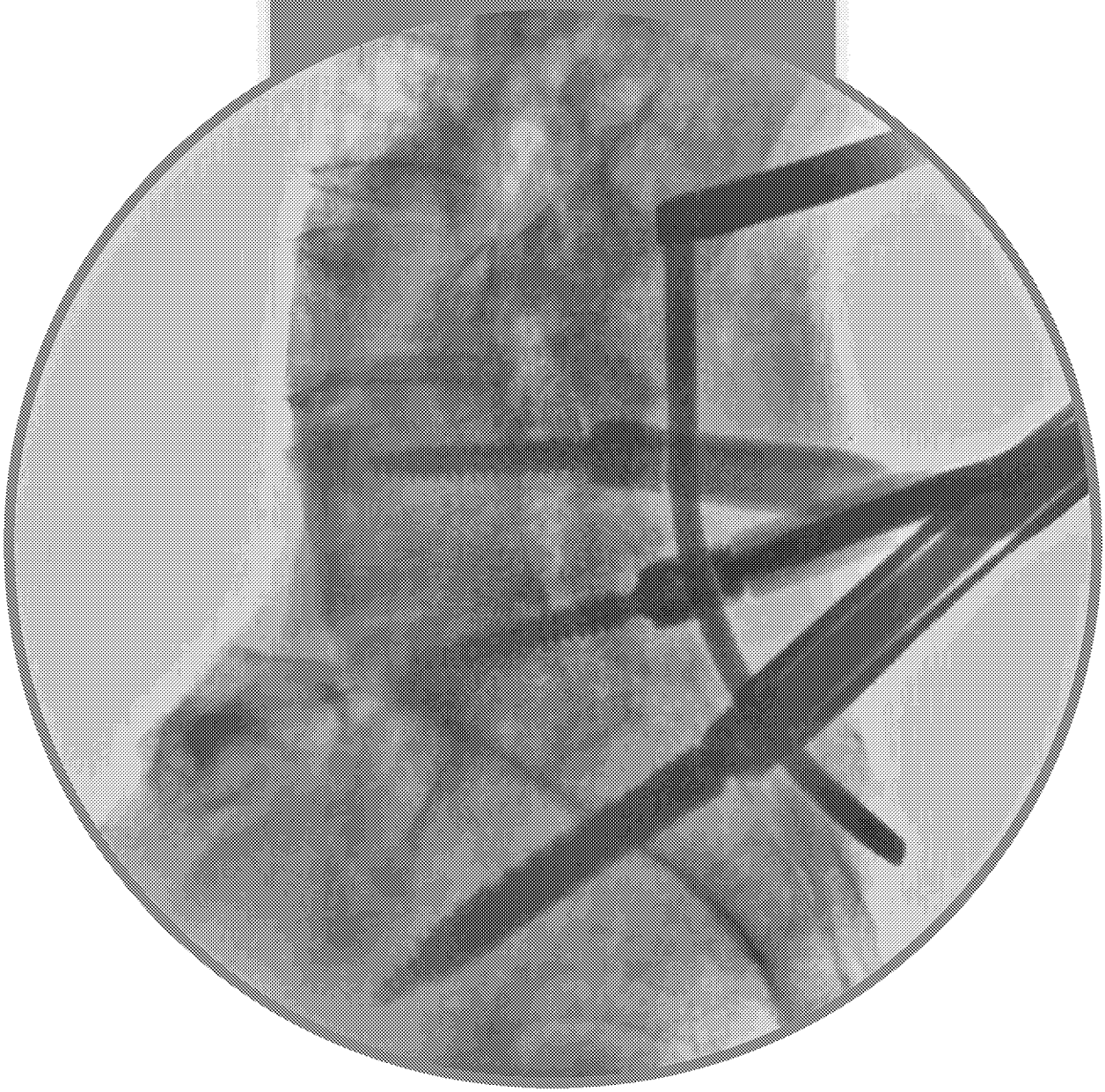


Figure 36

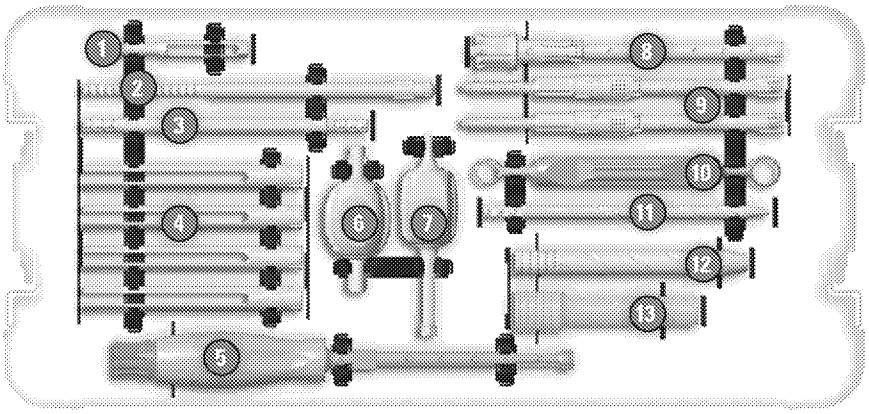
Minimally Invasive Surgery (MIS) Technique

Per surgeon preference or patient requirement, the iFuse Bedrock Granite Implant procedure can be performed under a minimally invasive surgical (MIS) technique. Utilizing the MIS instrumentation, in addition to the Open instrumentation, the subsequent pages outline the surgical steps to perform an MIS procedure.



Procedure: MIS Instrument Tray Layout

1. Reducer Driver MIS Reduction
2. Tower Attachment Tool
3. Rod Confirmation
4. Snap Towers Bedrock Granite MIS
5. Tower Remover
6. Head Wrench
7. Reducer Multi-Driver
8. Manual Tower Remover
9. Tower Reducers
10. Dual End Counter Torque (CT)
11. Dilator 1 (Stainless)
12. Dilator 2 (Black)
13. Dilator 3 (Black)



PRECAUTION: *The MIS technique and instruments are NOT compatible with the Closed Head Tulip Implants (P/N 100000CH).*

Procedure: Starting Point & Trajectory

- Make appropriate skin incision. Fluoroscopy may be used to determine the appropriate surgical site.

***NOTE**: A skin incision of approximately 2 cm is recommended to accommodate sequential dilation.*

- Advance an access needle in the desired trajectory to terminal depth (**Fig. 37).** Remove the access needle stylet and advance the Guidewire through the access needle to terminal depth, using the Guidewire Driver (optional).

***NOTE**: Access needle should accommodate a Guidewire maximum diameter of up to 1.45 mm.*

Guidewire Driver

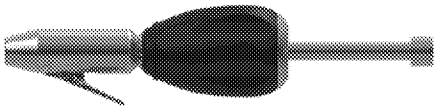
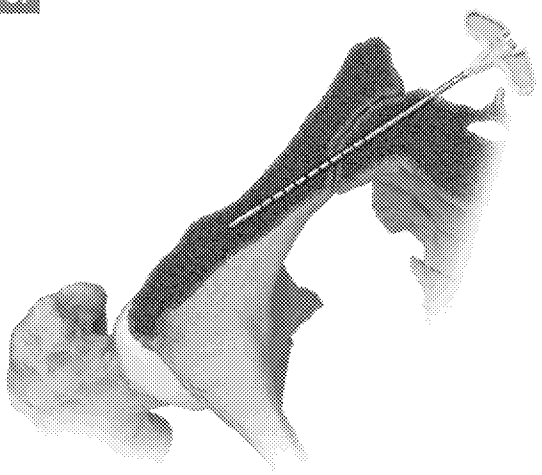


Figure 37

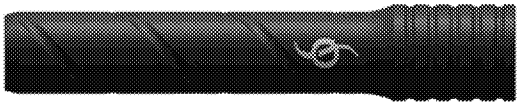


Procedure: Sequential Dilation

Figure 38 a

Figure 38 b

Figure 38 c



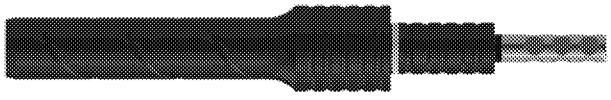
- Advance Dilators 1, 2 and 3 sequentially over the Guidewire **(Fig. 39).**

NOTE**: Laser markings on Dilator 1 and Dilator 2 will help confirm the distal tip of each sequential Dilator is seated against dorsal sacrum **(Fig. 40).

Instrument	Outer Diameter (mm)
Dilator 1	8.5
Dilator 2	15.4
Dilator 3	18.3

Figure 39

Figure 40



Procedure: Sequential Tapping

- Remove Dilators 1 and 2.
- Sequentially advance the desired Cannulated Taps over the Guidewire through Dilator 3.
- Advance the Cannulated Taps to terminal depth referencing the depth markings (60mm - 120mm in 10mm increments) on the Cannulated Tap as they enter the Dilator.

***NOTE**: Taps will allow for up to 110 mm in length through Dilator 3.*

- Sequentially tap as desired to full depth and selected Implant diameter **(Fig. 41).**

***NOTE**: Some users may elect to undersize with taps based on bone quality.*

Implant Size (mm)	Undersized	Line-to-Line
10.5	8.5, 9.5	10.5
11.5	8.5, 9.5, 10.5	11.5
Additional tap sizes are available upon request		

- Use fluoroscopy to confirm tap depth as the instrument advances.

NOTE:

- *Taps are true to size (i.e. 10.5 mm Tap is 10.5 mm major diameter).*
- *Black laser mark on proximal tap shaft is not visible when handles and QC Adapter are properly engaged **(Fig. 42).***
- *The Cannulated Taps have depth markings from 60mm to 120mm, in 10mm increments.*
- *A QC Adapter (Quarter Inch to Tri-lobe Adapter) for a Power Drill is provided.*

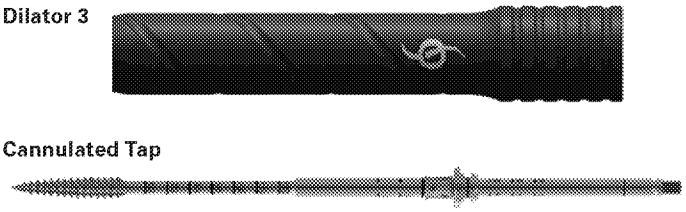


Figure 41

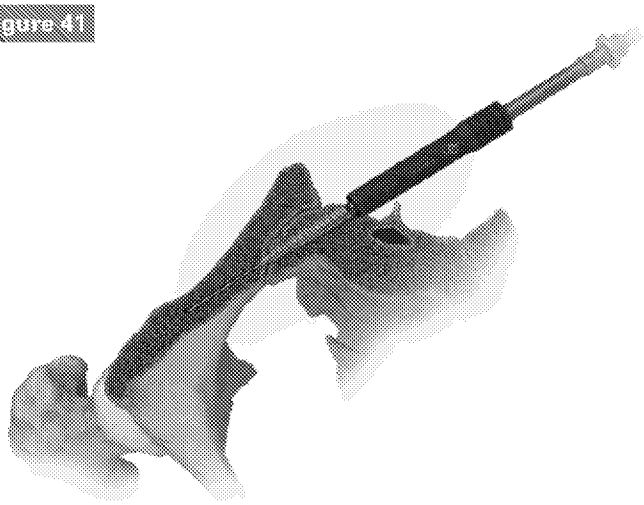
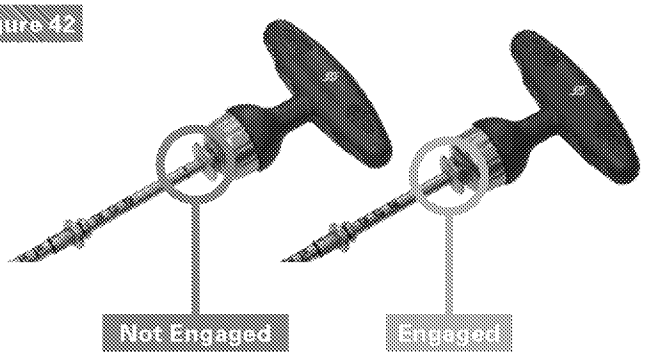


Figure 42



Procedure: Implant Assembly to Tower

- Unscrew the tube cap **(Fig. 43).**
- Aseptically transfer the sterile inner clamshell into the sterile field **(Fig. 44).**
- Remove the Implant and set screw from the sterile clamshell **(Fig .45).**
- Attach the Tower to the Implant tulip by aligning the Tower slots with the tulip rod opening, snapping it directly into place with downward pressure onto the tulip **(Fig. 46).**

Figure 43

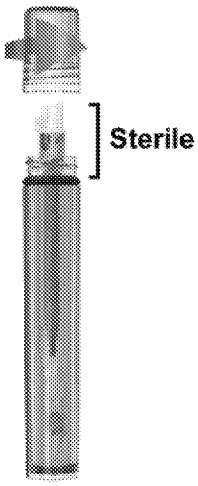


Figure 44

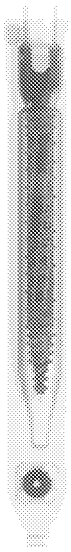
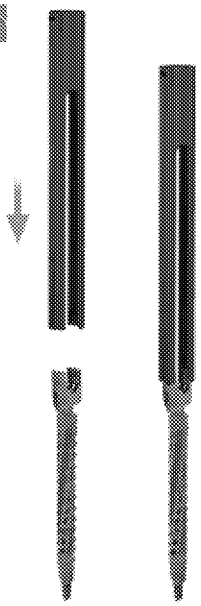


Figure 45

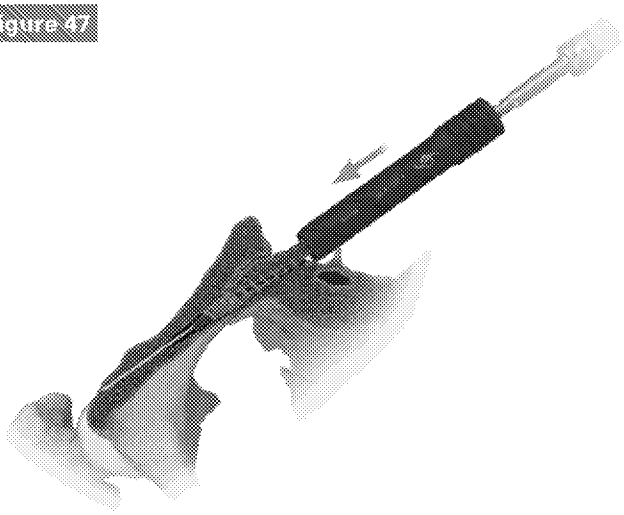
Figure 46



Procedure: Implant Placement

- Insert the Navigated Locking Driver tip through the Tower and engage it into the mating Implant drive feature.
- Secure the Implant onto the Driver by rotating the ribbed knob clockwise until tight.
- Slide the gold button down toward the Implant and into the locked position.
- Place the Implant, Tower, and Driver assembly over the Guidewire and through Dilator 3 **(Fig. 47).**
- Confirm Implant trajectory and placement under fluoroscopic visualization.
- When the Implant is fully seated, disengage the Driver by sliding the gold button towards the handle into the unlocked position.
- Unthread the Driver from the Implant tulip by rotating the ribbed knob counterclockwise.
- Remove the Driver, Dilator 3, and the Guidewire.

Figure 47



NOTE:

- *A Pin Driver may be used to back out the Guidewire.*
- *A Head Tuner is available to rotate Open Head Implant tulips **clockwise** to optimize favored angle. Do not rotate the tulip counterclockwise. Rotating counterclockwise may unthread the tulip head from the Implant body.*
- *A Depth Adjuster with Wings is available for use with Open Head Implants to make additional adjustment to implant depth.*

PRECAUTION: *Watch for Guidewire advancement during Implant placement. Guidewire may be removed if needed once the Implant tip crosses the sacroiliac joint.*

Procedure: Set Screw Placement & Optional Rod Reduction

- Upon ensuring that the rod is placed and seated within the Implant tulip and tower slots, set screw insertion may be achieved.
- Remove set screw from Implant clamshell or utilize additional set screw in the set screw caddy.
- Align distal "star" attachment guide with set screw.
- Apply downward pressure to Tower Reducer while pressing on proximal end to retain set screw **(Fig. 48).**
- Preset reduction to desired amount. Default setting should be set at 30 mm.
- Insert the Tower Reducer into the MIS Tower until locked into place **(Fig. 49).**

NOTE:

- *Align silver laser marks on sides of Tower Reducer and Tower attachment **(Fig. 49).***
- *Maximum reduction is 30 mm.*

Figure 48

Procedure: Optional Rod Reduction & Provisional Tightening

Engage the Reducer Multi-Driver

- Reduce rod into tulip by rotating gold knurled knob clockwise. Additional torque can be achieved by using Reducer Multi-Driver **(Fig. 50).**

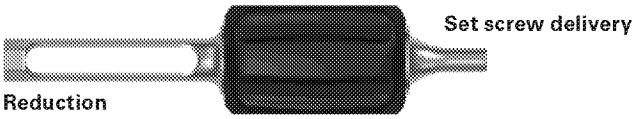


Figure 50

***NOTE**: Reducer Driver MIS Reduction with quarter-inch drive adapter is available for additional torque as needed.*

***PRECAUTION:** Do not over tighten. If torsional resistance is experienced, there may be soft tissue between the tulip and rod. Sufficiently remove tissue before proceeding.*

- Once the green ring on the inner shaft of the Tower Reducer is visible, the rod will be fully seated **(Fig. 51).** Use the silver set screw driver tip of the Reducer Multi-Driver to deliver set screw.
- Rotate set screw inserter shaft ¼ turn counterclockwise to positively engage set screw into tulip.
- User should feel threads skip over and engage. Rotate clockwise to provisionally place set screw.
- Remove the Tower Reducer by depressing the gold clips to release the Reducer from the Tower.

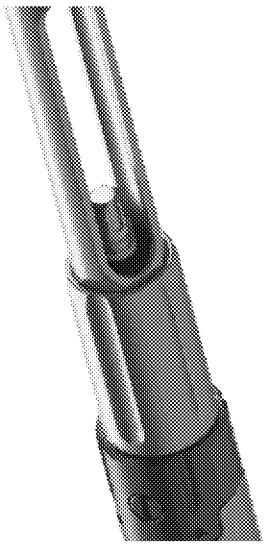
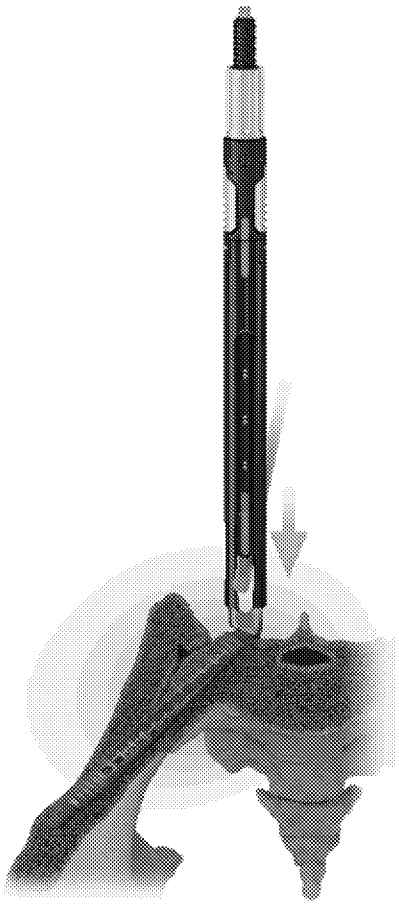


Figure 51



***NOTE**: Excess pressure on the Reducer can make releasing clips more challenging. If so, unthread the Reducer 1 full turn, or until pressure is released and clips can be properly depressed for removal.*

Procedure: Final Tightening

- Assemble the T-handle **(Fig. 52 a)** to the Torque Limiting Adapter **(Fig. 52 b)** and then to the T30 Final Driver **(Fig. 52 c).**
- Securely attach the larger, black aperture of the Dual End Counter Torque **(Fig. 52 d)** to the proximal end of Tower **(Fig. 52 e).**
- Insert final tightening assembly through the Tower and fully seat the distal tip into the set screw.
- While final tightening with the T-Handle, firmly hold the Dual End Counter Torque until a minimum of two audible clicks are heard or tangibly felt.

Figure 52 a

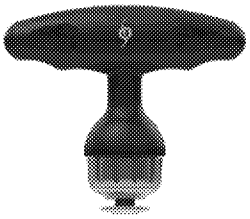


Figure 52 b

Figure 52 c

Figure 52 d

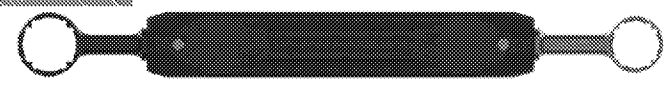
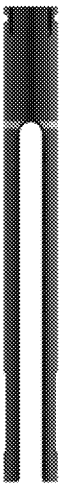


Figure 52 e



Procedure: Tower Re-Engagement Tool (Optional)

- If the Tower becomes detached from the tulip, the Tower Attachment Tool may be used to replace the Tower. Advance the Tower Attachment Tool into the tulip, aligning the flat proximal ends within the tulip slots.
- Advance the Tower over the Tower Attachment Tool until the distal Tower flanges are secured onto the tulip.

***NOTE**: The Tower Attachment Tool is cannulated and may be advanced over a Guidewire.*

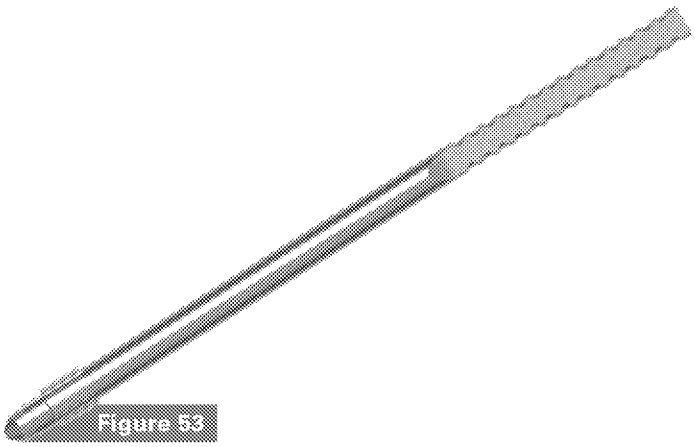
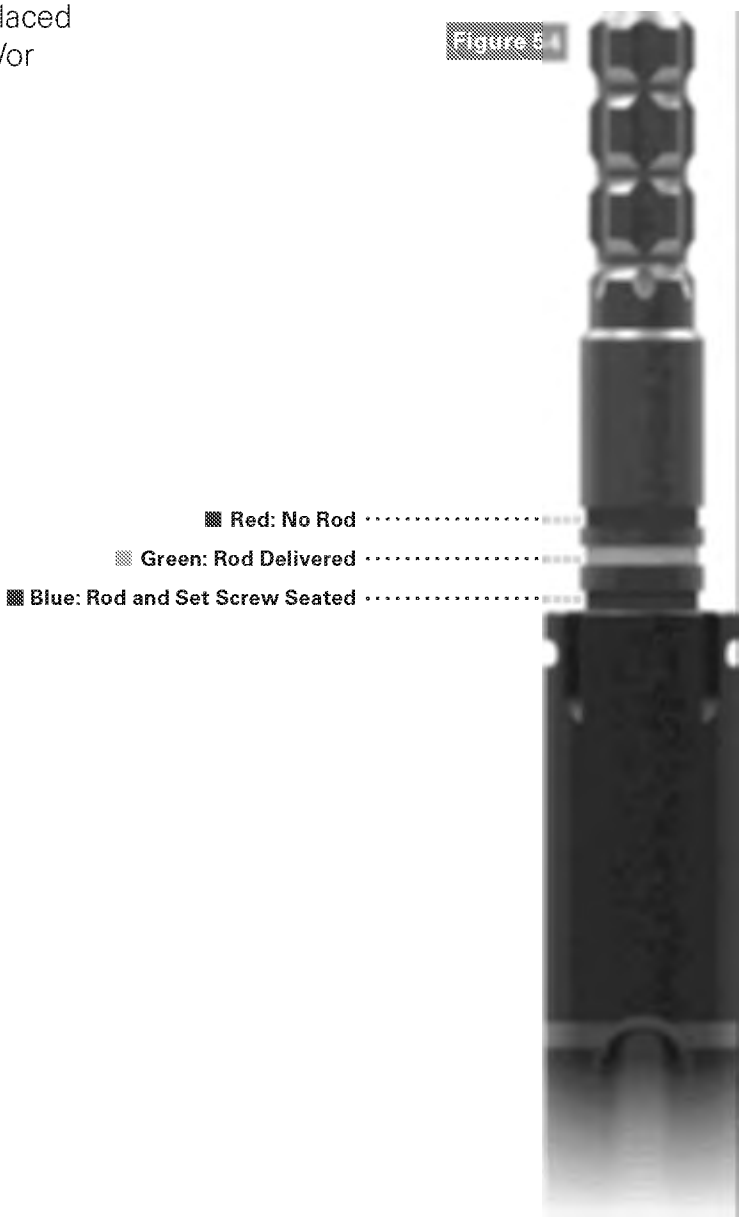


Figure 53

Procedure: Rod Confirmation Tool (Optional)

- The Rod Confirmation Tool may be placed through the Tower to assess rod and/or set screw placement.



Procedure: Tower Removal

- Ensure that the green ring of the Manual Tower Remover inner shaft is visible by rotating the gold barrel counterclockwise **(Fig. 56).**
- Insert the Manual Tower Remover into the Tower by aligning the silver laser marks. Advance the Manual Tower Remover until the gold tabs engage into the Tower slots.
- Rotate the gold barrel clockwise until the green ring is no longer visible. Pull up on the Manual Tower Remover to remove Tower.

NOTE:

- *If desired, a Tower Remover may be used to disengage the Tower from the Implant tulip* ***(Fig. 55).***
- *Apply downward pressure until engaged with Tower and dial changes from "Ready" to "Remove"* ***(Fig. 57).***
- *Hold Tower and pull upwards to remove.*
- *Upon removal, disengage the Tower from the Tower Remover by turning the gold knob clockwise to "Ready".*

Figure 55

Optional: Tower Remover

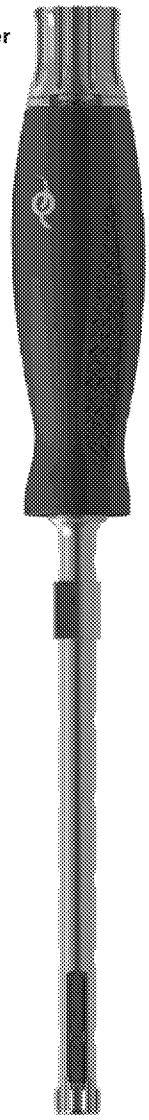
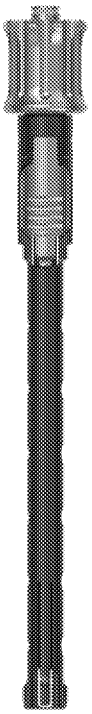


Figure 56



Manual Tower Remover

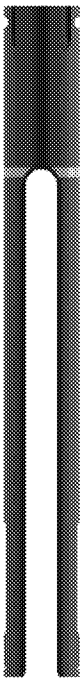


Figure 57

Background: Bedrock Granite Instrumentation allows for surgeons to perform the procedure while navigating under Medtronic StealthStation.

- Reconfirm accuracy by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.
- If the stereotactic navigation system does not appear to be accurate despite troubleshooting, do not rely on the navigation system.
- The subsequent steps cover only navigation-related instrumentation. All other technique steps may be referenced in the OPEN and MIS sections of this technique manual.

Figure 58

Procedure: Instrument Assembly

- Select desired StealthStation™ NavLock array **(Fig. 59 a).**
- Select desired Bedrock Granite Taps and Navigated Locking Driver **(Fig. 59 b).**
- Attach array to proximal instrument engagement feature.
- Connect desired handle **(Fig. 59 c).**

***NOTE**: For Implant assembly to Navigated Locking Driver: See Page 12 of OPEN Technique*

Figure 59

Procedure: Tool Card Selection

- Select and register the following instruments according to the displayed Medtronic Tool Card Instrument.

Part Number	Granite Instrument	Medtronic Tool Card
400268	Bedrock Granite Navigation, Locking Driver	NavLock Lumbar Probe **PN 9734679**
400238-XXXX 400302-XXXX	Bedrock Granite Tap	NavLock Lumbar Probe **PN 9734679**

Procedure: Instrument Registration

Taps & Navigated Locking Driver

- A pop-up window will appear with available instruments for pairing. Use the search box to select your desired NavLock array and click "add".
- A pop-up window will appear prompting default tip selection. Click on the drop down and select "Awls and Probes". Then select "Probe Lumbar".
- With another array of your choice, follow the same steps and selections to register the Navigated Locking Driver similarly, as a Lumbar Probe.

Figure 60

Figure 61

Figure 62

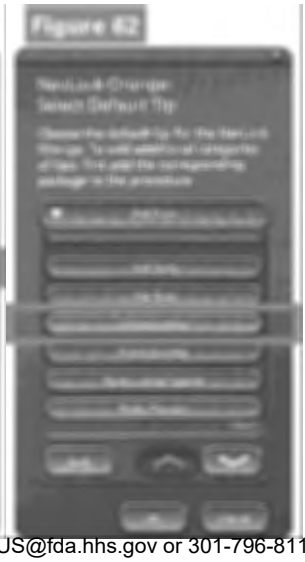
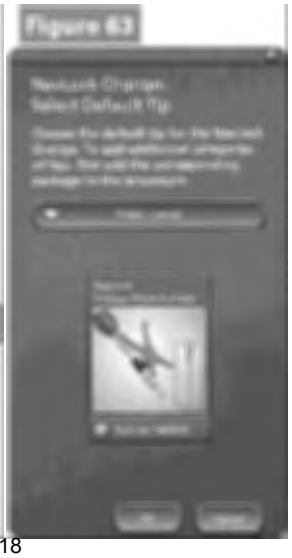


Figure 63



Procedure: Projecting Instruments

Taps

- When projecting for the Taps, utilize a projection of the chosen tap diameter and a negative length **(Fig. 64).**

Figure 64

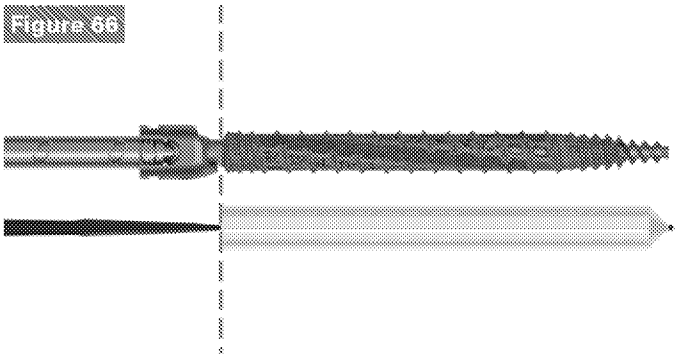
Navigated Locking Driver

- When projecting for the Navigated Locking Driver, utilize a projection of the chosen Implant diameter and length **(Fig. 65).**

NOTE**: The projection accounts for length and diameter of the Implant, but not the tulip head **(Fig. 66).

Figure 65

Figure 66



The iFuse Bedrock Granite system includes various removal tools. Upon need for Implant removal, please follow the subsequent steps and methods for removal.

Scenario 1:

- If Implant needs to be removed, remove set screw and rod. Use Cannulated Implant Depth Adjuster with Wings to remove **(Fig. 67).**

Figure 67

WARNING: *iFuse Bedrock Granite Implants have porous surfaces that are designed to integrate with bone (i.e., bone ongrowth and ingrowth). Growth of bone onto/into the Implants may make late removal of Implants challenging. Trephines, chisels or other instruments may be needed to separate the implant from surrounding bone to allow removal*

Scenario 2

- A Bedrock Granite Extraction Instrument is available upon request should the inner shank become dislodged from the sleeve **(Fig. 68).**

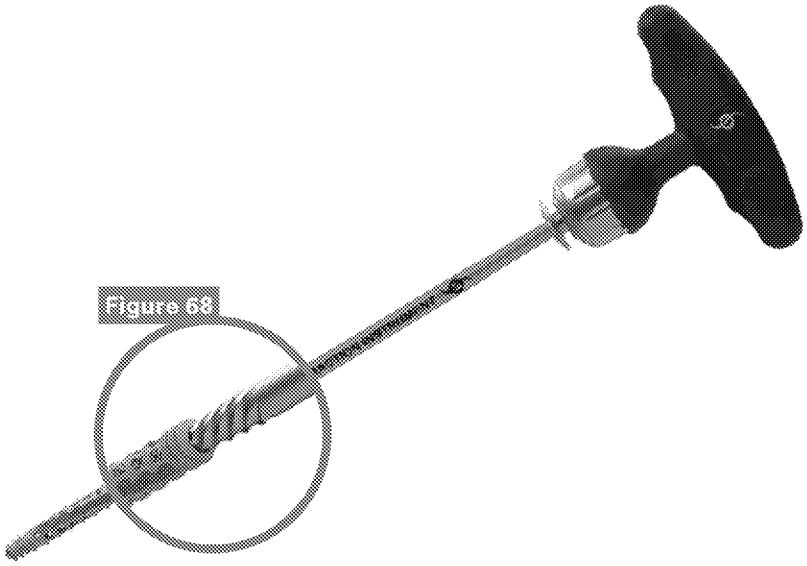


Figure 68

Product Catalog: iFuse Bedrock Granite Instrumentation

Description	Part No.
Bone Probe, Curved	400263
Bone Probe, Straight	400264
Navigation, Locking Driver	400268
Head Turner	400269
Set Screw Starter, Axial	400270
Axial Reducer	400338
Counter Torque	400272 -0100
Bedrock Granite Cannulated Implant Depth Adjuster with Wings	400281
Bedrock Granite 8.5mm Awl Tip Tap	400298-0850
Bedrock Granite 9.5mm Awl Tip Tap	400298-0950
Bedrock Granite 10.5mm Awl Tip Tap	400298-1050
Bedrock Granite 8.5mm Cannulated Tip Tap	400302-0850
Bedrock Granite 9.5mm Cannulated Tip Tap	400302-0950
Bedrock Granite 10.5mm Cannulated Tip Tap	400302-1050
T-Handle, Ratcheting, Quarter Square, Low Profile	501621
Inline Handle, Ratcheting, Quarter Square, Low Profile	501622
Bedrock Granite Guidewire Sharp (1.4mm) — Disposable Item	501168
Guidewire Driver	501323
QC Adapter, Quarter Inch to Trilobe	501417
Bedrock Granite Measurement Probe	501167
Torque Limiting Adapter 115 in-lb	501192

Product Catalog: iFuse Bedrock Granite Instrumentation

Description	Part No.
T30 Final Driver	501199
Threaded Reducer Extension	501353
Tower Remover	400274
Head Wrench	400275
Reducer Multi-Driver	400276
Manual Tower Remover	400278
Bedrock Granite Dilator 2	400279
Dual End CT	400280
Tower Reducer	400294
Bedrock Granite Dilator 1	501213
Snap Tower Bedrock Granite MIS	501224
Bedrock Granite Dilator 3	501235
Rod Confirmation	501350
Reducer Driver MIS Reduction	501382
Tower Attachment Tool	501351
Set Screw Caddy	501402

Available Upon Request	
Bedrock Granite Sleeve Extraction Instrument	501349
QC Adapter, Quarter Inch to POWEREASE	501485
Threaded Rod Reducer	400271-0100
Bedrock Granite 11.5mm Awl Tip Tap	400298-1150
Bedrock Granite 11.5mm Cannulated Tip Tap	400302-1150

Indications For Use, Contraindications, Warnings and Precautions

INDICATIONS FOR USE

The iFuse Bedrock Granite® Implant System is intended for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screws with 5.5- or 6.0-mm posterior rods made from either titanium alloys or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments to treat progressive spinal deformities (i.e scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the iFuse Bedrock Granite Implant System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MRI, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

ADDITIONAL COMPATIBILITY INFORMATION

Compatible pedicle screw system rods include all the conditions listed below

1. 5.5- or 6.0-mm in diameter
2. Cross section is circular and non-threaded
3. Made of:
   - Titanium alloy (Ti-6Al-4V ELI per ASTM F136),
   - Cobalt chrome (Co-28Cr-6Mo per ASTM F1537 or 35Co-35Ni-20Cr-10Mo per ASTM 562)
4. Not additively manufactured
5. Not coated with additional materials (e.g., Hydroxyapatite)
   - Note: Anodization (color or type II) does not alter the material

CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

Please refer to the Instructions for Use of the connected pedicle screw system for a complete list of all warnings, precautions and possible adverse events associated with its use.

CONTRAINDICATIONS

The following conditions may reduce the chance of a successful outcome and should be taken into consideration by the surgeon.

- Deformities or anatomic variations that prevent or interfere with iFuse Bedrock Granite Implant placement.
- Tumor of sacral or iliial bones that could adversely affect implant placement.
- Active infection at treatment site.
- Allergy to metal components.
- Use of incompatible materials from other systems.

WARNINGS

1. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
2. Inspect implants and instruments for damage prior to use. Do not use any component from an opened or damaged package or use any device that appears damaged or worn; do not attempt to repair damaged devices. Use of damaged devices may result in patient injury.
3. Do not reuse implants under any circumstances. A used implant should be discarded.
4. Do not use implants after the expiration date, as use of expired devices may result in patient harm.
5. Care should be used during surgical procedures to prevent damage to the device(s), and injury to the patient.
6. iFuse Bedrock Granite Implants have porous surfaces that are designed to integrate with bone (i.e., bone ongrowth and ingrowth). Growth of bone onto/into the implants may make late removal of implants challenging. Trephines, chisels or other instruments may be needed to separate the implant from surrounding bone to allow removal.
7. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.

   CAUTION: This device has not been tested with all FDA-cleared spinal rods. Performance may vary.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury.

PRECAUTIONS

1. The iFuse Bedrock Granite Implant System should only be used by physicians familiar with pelvic fixation techniques as illustrated in the SI-BONE iFuse Bedrock Granite Surgical Technique Manual.
2. Consult the Pedicle Screw System Surgical Technique Manual for use instructions and warnings, precautions, and recommendations relevant to the pedicle screw system.
3. Pay careful attention to selection of implant size. Pre- operative X-rays and/or CT scan may be helpful in selecting implant size.
4. Select implant size sufficient to ensure adequate fixation within the pelvis given the planned trajectory and pelvic anatomy.
5. Use sterile technique when handling the implant and during the procedure to maintain sterility and minimize risk of infection.
6. Care should be used in the handling and storage of the implants. Instruments should be protected during storage and from corrosive environments.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

There are potential risks associated with the iFuse Bedrock Granite Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit *www.si-bone.com/label*.

iFuse
Bedrock Granite®
Implant System

SI-BONE®

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SI-BONE iFuse Implant System® Instruments Hospital Cleaning and Sterilization Instructions, USA

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Instruction for Use and Symbols Glossary:
www.si-bone.com/label

DESCRIPTION

The iFuse family of instruments include the iFuse Implant System®, iFuse Implant System (iFuse 3D™), iFuse TORQ® Implant System, and iFuse Bedrock Granite® Implant System. The instruments are reusable or disposable, manual surgical instruments provided in an instrument set that is used as part of the iFuse Implant System to facilitate placement, implantation, and removal of iFuse implant devices.

The instruments are supplied **non-sterile** and must be cleaned and sterilized prior to use. The iFuse Implant is provided separately and supplied sterile. Refer to the iFuse Implant System Instructions for Use. Note: Single-use devices that have been used should be disposed of immediately after use. For a complete list of all SI-BONE manual surgical instrument sets, please refer to the Surgical Technique Manuals available on the SI-BONE website at www.si-bone.com/label.

INDICATIONS FOR USE

Refer to the iFuse Implant System, iFuse Implant System (iFuse 3D), iFuse TORQ Implant System, and iFuse Bedrock Granite Implant System Instructions for Use for complete Indications for Use at www.si-bone.com/label.

MATERIALS

The SI-BONE instruments are manufactured from one or more of the following materials: durable alloys and polymers such as stainless steel, titanium alloy, aluminum alloy, polyetheretherketone (PEEK), and silicone.

CONTRAINDICATIONS

Refer to the contraindications listed in the iFuse Implant System, iFuse Implant System (iFuse 3D), iFuse TORQ Implant System, and iFuse Bedrock Granite Instructions for Use at www.si-bone.com/label.

INSPECTION

Inspect all instruments prior to use for possible damage, unacceptable wear, or non-functioning components. Contact your local sales representative for replacement of damaged instrument(s).

WARNINGS

- Single-use devices (e.g., drill bits, pins, and guidewires) must not be reused as they are not designed to perform as intended after the initial use.
- Caution should be exercised when handling instruments and implants, as they are sharp and can puncture or tear gloves, or cause injury.
- Follow the instructions and warnings issued by the suppliers of any cleaning solutions and equipment used.
- Avoid exposure to hypochlorite solutions and solutions containing iodine or high chlorine content, as these will promote corrosion.
- Cleaning agents with a pH of 7 – 9 are recommended.
- Highly alkaline conditions (pH > 11) can damage instruments (i.e., aluminum parts).
- Manual pre-cleaning must be performed prior to Automated Cleaning for all instruments.
- Soiled or used devices should not be loaded into the instrument tray for cleaning in a mechanical washer. Soiled instruments must be processed separate from trays and cases. SI-BONE instrument trays are designed to be an organization tool for steam sterilization process, a storage tool for all medical devices, and an organizational tool for surgery.
- The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665.

CLEANING THE INSTRUMENTS

Clean instruments using the Automated Cleaning Process (**Table 1**) or the Manual Cleaning Process (**Table 3**).

Table 1. Automated Cleaning Process

	Pre-Cleaning Instructions
1	Clean instruments as soon as possible after use, thoroughly rinsing the instruments with warm tap water to remove gross contamination. Do not allow blood and/or debris to dry on the instruments.
2	Disassemble Navigation Impactor/Removal Adapter (see **Figure 7**).
3	DO NOT disassemble the "pinned" Soft Tissue Protector assembly (see **Figure 6**).
4	DO NOT disassemble the screw from the Adjustable Parallel Pin Guide (see **Figure 4**).
5	**Dispose of any pins (e.g., guide wires, Steinmann pins, K-wires) and iFuse Implant System Drill Bits used in the procedure.** **Note:** iFuse TORQ Implant System Drill Bits are reusable.
6	Fully immerse all instruments in a mildly alkaline, enzymatic cleaner, such as MediClean® at 0.5 - 2%, at ≤40°C and actuate all features so the enzymatic cleaner contacts all mated surfaces. Remove gross soil using a soft bristled brush.
7	Soak instruments for 10-30 minutes. Flush all lumens and hard to reach areas of the instruments with the prepared detergent using an appropriately sized syringe or pipette filled with the prepared cleaning solution a minimum of 3 times
8	Rinse the instruments with cold tap water for 1 minute. Remove remaining gross soil using a soft-bristled, nylon brush. Pay particular attention to crevices, lumens, mated surfaces, connectors, and other hard-to-clean areas. Lumens and hard to reach areas should be cleaned with a long, narrow, soft-bristled brush (i.e., pipe cleaner brush). Do not use metal scouring pads.
9	Flush lumens with water a minimum of 3 times using a syringe or pipette.
	Automated Cleaning Process Instructions
10	Load the instruments so that the lumens/blind holes can drain.
11	Using a validated washer disinfector and a mildly alkaline enzymatic cleaning agent intended for use in an automated cleaning process, use the minimum cycle parameter set points in **Table 2**.
12	After the completion of the washer cycle, visually inspect the instruments for remaining soil in a well-lit area; no visible soil should be left on the device(s).
13	If devices are still wet after the automated cleaning cycle, thoroughly dry the devices using a clean, lint-free cloth. If needed, use filtered pressurized air at <40 psi to aid in drying.
14	Return instruments to their designated locations in the cleaned SI-BONE trays as applicable.
	End of Automated Cleaning Process

Table 2. Automated Washer/Disinfector Cleaning Cycle Parameters

Cycle	Time (minutes:seconds)	Minimum Temperature	Detergent/Water
Pre-Cleaning	2:00	Cold	Tap
Cleaning	5:00	Heated Tap (55°C)	MediClean® (per the manufacturer's instructions)
Rinse	2:00	Heated (70°C)	Reverse Osmosis (RO) Water
Thermal Rinse	1:00	Heated (90°C)	RO Water
Dry	26:00	Heated (85°C)	N/A

Table 3. Manual Cleaning Process

	Manual Cleaning Process Instructions
1	Clean instruments as soon as possible after use, thoroughly rinsing the instruments under running warm tap water to remove gross contamination. Do not allow blood and/or debris to dry on the instruments.
2	Disassemble Navigation Impactor/Removal Adapter (see **Figure 7**).
3	DO NOT disassemble the "pinned" Soft Tissue Protector assembly (see **Figure 6**).
4	DO NOT disassemble the screw from the Adjustable Parallel Pin Guide (see **Figure 4**).
5	**Dispose of any pins (e.g., guide wires, Steinmann pins, K-wires) and iFuse Implant System Drill Bits used in the procedure.** **Note**: iFuse TORQ Implant System Drill Bits are reusable
6	Prepare a neutral pH enzymatic detergent or equivalent such as Enzol® per manufacturer's directions at 1 oz/gallon using lukewarm tap water.
7	Fully immerse the instruments in the prepared detergent and actuate all features so the detergent contacts all mated surfaces.
8	Flush all hard-to-reach areas of the instruments with the prepared detergent using an appropriately sized syringe and allow them to soak for a minimum of 10 minutes.
9	Following the minimum 10-minute soak, use a soft-bristled, nylon brush to gently scrub the instruments until all visible soil has been removed. Actuate device to allow access to hard-to-reach areas. Pay particular attention to crevices, lumens, mated surfaces, connectors, and other hard-to-clean areas. Lumens and hard to reach areas should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush). Do not use metal scouring pads.
10	After brushing, use an appropriately sized syringe to thoroughly flush the prepared detergent through all lumens, holes and other difficult-to-reach areas.
11	Thoroughly rinse the instruments under running tap water for a minimum of 1 minute. Flush all lumens, holes and hard to reach areas using an appropriately sized syringe filled with tap water.
12	Prepare an enzymatic detergent such as Enzol® per manufacturer's directions at 1 oz/gallon using lukewarm tap water in a sonication unit.
13	Completely submerge the instruments in the prepared detergent.

14	Flush all hard-to-reach areas of the instruments with the prepared detergent using an appropriately sized syringe, and sonicate for 10 minutes at 45-50 kHz
15	Minimum 1-minute rinse under running tap water. Thoroughly flush lumens, holes, and other difficult-to-reach areas using an appropriately sized syringe filled with tap water.
16	Thoroughly dry the instruments using a clean lint-free cloth.
17	Visually inspect the instruments for cleanliness. If soil is visible, repeat the cleaning procedures outlined above.
18	Return instruments to their designated locations in the cleaned SI-BONE tray as applicable.
End of Manual Cleaning Process	

INSTRUMENT VERIFICATION PRIOR TO STERILIZATION

1. Visually inspect the instruments for corrosion, pitting, discoloration, or cracking, which might indicate excessive wear. Check the instruments to ensure the legibility of the laser marking. If an instrument is damaged or shows signs of unusual or excessive wear, SI-BONE will replace the instrument(s).

   Note: Sterilize damaged parts separately and prior to shipment to SI-BONE for replacement.

2. For disposable parts (Pins, Guidewires, and iFuse Implant System Drill Bits), visually inspect and dispose if parts show signs of prior use.
3. Visually inspect the instrument tray and content surfaces for dry blood and/or tissue to ensure cleanliness. As applicable, ensure that the Aesculap SterilContainer System is clean.
4. Inspect the specific instrument features as described in **Table 4**.
5. Return instruments to their designated locations in the cleaned SI-BONE tray as applicable.
6. Instruments not stored in the tray should be cleaned and sterilized individually per validated hospital procedures. Individual instruments such as silicone impact dampeners may be placed in a peel pack pouch or a generic sterilization tray and positioned for optimal drainage.

Table 4. Instrument Inspection

Instrument	Description of Inspection
All Instruments	• Check inner cannula and threads to ensure no damage or residual tissue or debris (See examples in **Figures 1, 2, 8, 11**). • Check blind holes (does not go through the whole instrument) to ensure no residual tissue or debris (See example in **Figure 3**). • Check sliding mechanisms and/or actuating parts to ensure proper function and cleanliness (See examples in **Figures 4, 9, 10**). • Check the slot and cutting surfaces of the Broach to ensure no damage or residual tissue or debris (See example in **Figure 5**).
iFuse TORQ Instruments	• Check the latching mechanisms and connectors on the Soft Tissue Protectors with the Latching Handle (See examples in **Figures 12 – 13**). • Check the connection of the 1/4" to Trilobe Adapter, Inline Handle, T-Handle, and Nav Adapters (See examples in **Figures 14 – 15**) with the appropriate mating Drill, Tap, or Torx Driver. • Check the button release mechanism on the Driver Sleeves with the Torx Driver (See examples in **Figures 16** and **17**).
iFuse Bedrock Granite Instruments, Open and iFuse Bedrock Granite+ Instruments	• Check the locking and ratcheting mechanisms of the Navigation Locking Driver (See example in **Figure 18**). • Check the latching arms and handle threads of the Axial Reducer (see example in **Figure 19**). • Check the latching mechanism of the Guidewire Driver (see example in **Figure 20**). • Check the lid and internal surfaces of the Set Screw Caddy (see example in **Figure 21**) and the Torx drive, threads, and cannula of each Set Screw to ensure no damage to the set screws has been sustained (see example in **Figure 22**) inside the Set Screw Caddy.

Instrument	Description of Inspection
	*Note: The Set Screw Caddy contains Bedrock Granite Set Screws, which are **implants**. Refer to the Sterilization Procedure below regarding the use of Biological Indicators for Sterilization.*
iFuse Bedrock Granite Instruments, MIS	• Check the gold release knob, the distal tip of the instrument, and the sliding lock on the Tower Remover (see example in **Figure 23**). • Check the distal tip and the shaft of the Manual Tower Remover (see example in **Figure 24**). • Check the distal tip and the shaft of the Tower Reducer (see example in **Figure 25**). • Check the slots and distal tip of the tabs on each Tower (see example in **Figure 26**)

STANDARD, XL, AND NAVIGATION INSTRUMENTS

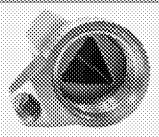


Figure 1
Soft Tissue Protector Inner Cannula

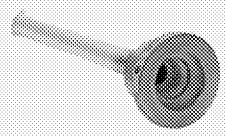


Figure 2
Drill/Pin Sleeve Inner & Outer Threads

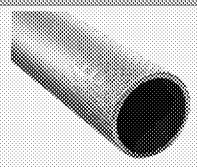


Figure 3
Soft Tissue Protector Handle

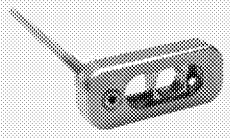


Figure 4
Adjustable Parallel Pin Guide

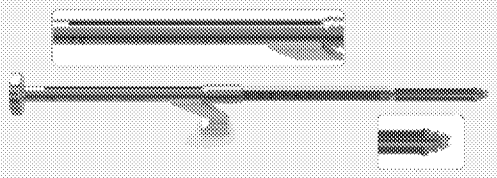


Figure 5
Broach

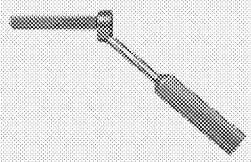


Figure 6
Pinned Soft Tissue Protector

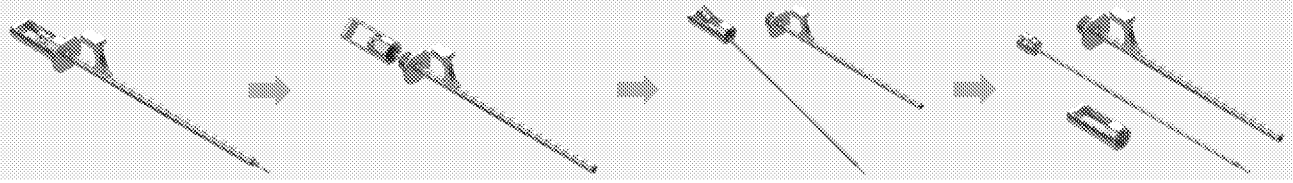


Figure 7
Nav. Impactor/Removal Adapter Assembly

RADIOLUCENT INSTRUMENTS

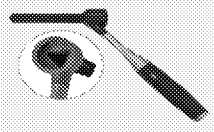


Figure 8
Soft Tissue Protector

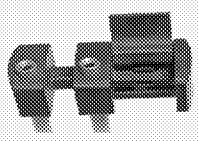


Figure 9
Variable Parallel Pin Guide

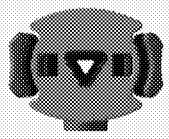


Figure 10
Orientation Guide

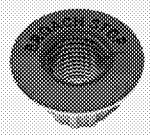


Figure 11
Adjustable Broach Stop

IFUSE TORQ INSTRUMENTS

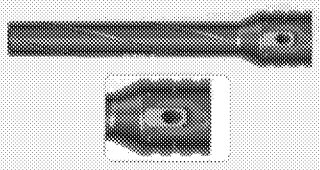


Figure 12
Soft Tissue Protector 1

Figure 13
Latching Handle

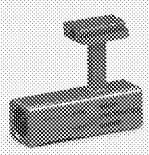


Figure 14
Nav. Adapter – Driver

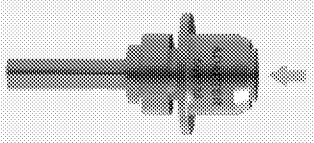


Figure 15
1/4" to Trilobe Adapter

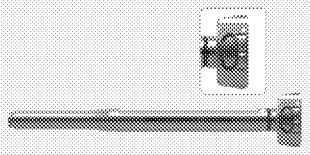


Figure 16
Driver Sleeve 1

Figure 17
Torx Driver

IFUSE BEDROCK GRANITE INSTRUMENTS, OPEN

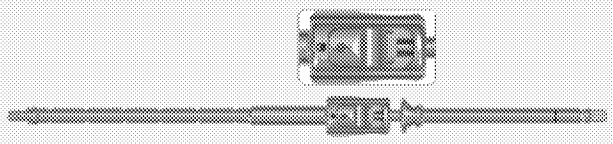


Figure 18
Navigation, Locking Driver

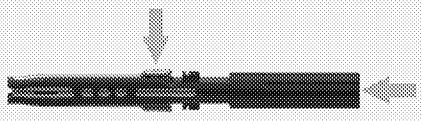


Figure 19
Axial Rod Reducer

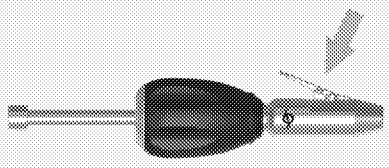


Figure 20
Guidewire Driver

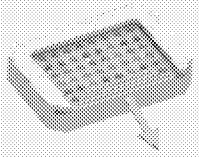


Figure 21
Set Screw Caddy

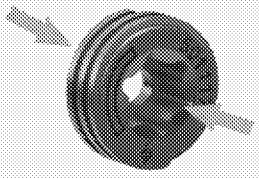


Figure 22
Set Screw

IFUSE BEDROCK GRANITE INSTRUMENTS, MIS

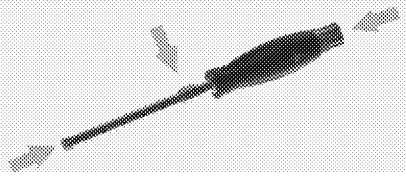


Figure 23
Tower Remover

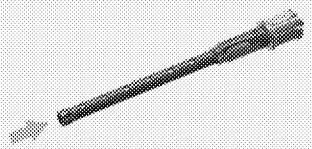


Figure 24
Manual Tower Remover

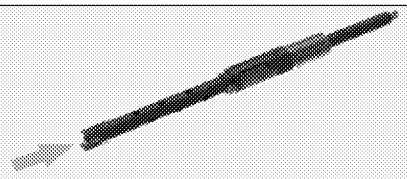


Figure 25
Tower Reducer

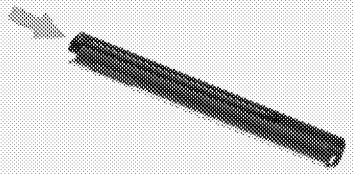


Figure 26
Tower

STERILIZATION PROCEDURE

The SI-BONE instrument set should be covered in an FDA-cleared blue wrap (double wrapped) using steam sterilization tape, and the instruments must be steam sterilized prior to use, using the sterilization parameters shown below.

Aesculap® SterilContainer™ System

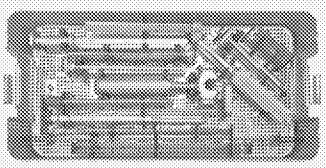
The Aesculap SterilContainer System (P/N 400326 or P/N 400329) is a reusable container system used for the packaging of instrument tray sets prior to, during, and after steam sterilization. It consists of a container bottom and container lid pair (JK444 with JK489 or JN445 with JK490). The container lids (JK489 and JK490) are perforated and include retention plates for filters. For the complete Instructions for Use, refer to the Aesculap SterilContainer Instructions for Use. Instrument Sets shown in the table below can be sterilized inside of P/N 400326 or P/N 400329 with the parameters shown, unless otherwise indicated.

Biological Indicators (BIs) for Sterilization

BIs contained within a process challenge device (PCD) are to be used when sterilizing instrument trays containing implants per AAMI ST79:2017. The Bedrock Granite Instrument Set, Open (P/N 400309) and the Bedrock Granite+ Instrument Set (P/N 400381) contain implants (501117 Bedrock Granite Set Screw).

STERILIZATION PARAMETERS

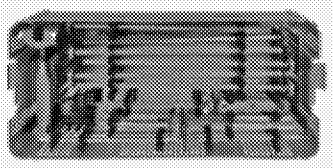
Sterilizer Type	Preconditioning Pulses	Minimum Temperature	Full Cycle Time	Minimum Dry Time
Pre-Vacuum	3	132°C	4 minutes	See below



Wrap
40 minutes

Aesculap
30 minutes

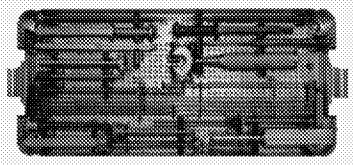
XL INSTRUMENT SET (P/N 400062)



Wrap
40 minutes

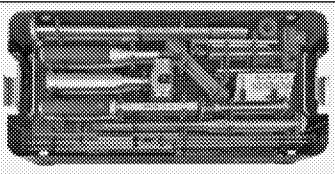
Aesculap
30 minutes

REMOVAL SYSTEM INSTRUMENT SET (P/N 400132)



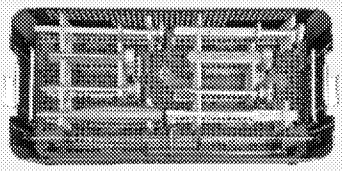
Wrap/ Aesculap
30 minutes

STANDARD INSTRUMENT SET (P/N 400099)



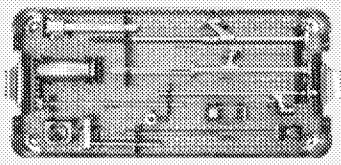
Wrap/ Aesculap
30 minutes

RADIOLUCENT INSTRUMENT SET (P/N 400091)



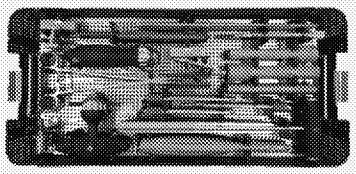
Wrap/ Aesculap
30 minutes

REVISION INSTRUMENT SET (P/N 400145)



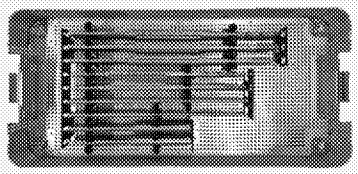
Wrap/ Aesculap
30 minutes

NAVIGATION INSTRUMENT SET (P/N 400200)



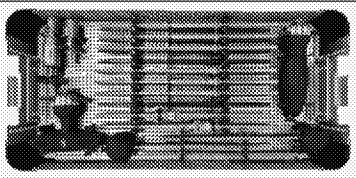
Wrap/ Aesculap
30 minutes

IFUSE TORQ INSTRUMENT SET (P/N 400287)



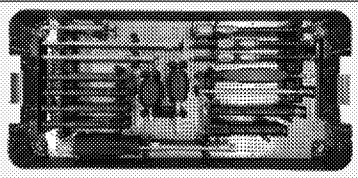
Wrap/ Aesculap
30 minutes

IFUSE TORQ INSTRUMENT SET, REVISION (P/N 400289)



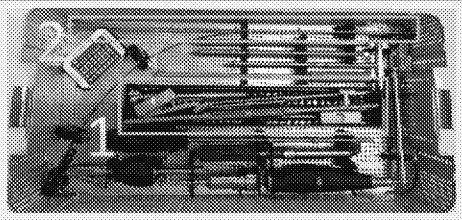
Wrap/ Aesculap
30 minutes

BEDROCK GRANITE INSTRUMENT SET, OPEN (P/N 400309)



Wrap/ Aesculap
30 minutes

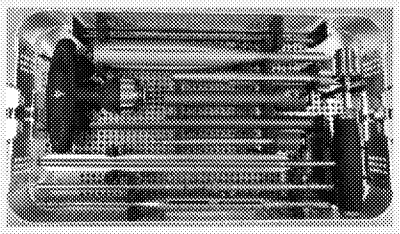
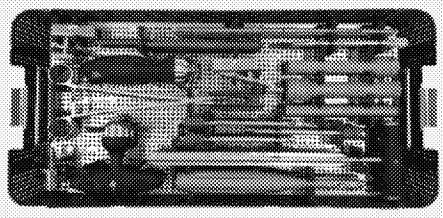
BEDROCK GRANITE INSTRUMENT SET, MIS (P/N 400310)



Wrap/ Aesculap
30 minutes

BEDROCK GRANITE+ INSTRUMENT SET (P/N 400381)
Bedrock Granite Instrument Set (P/N 400309) with additional iFuse TORQ instruments in the utility mat area (1) and one Exchange Pin in the Guidewire Sharp brackets on the long edge of the tray (2)

STERILIZATION PARAMETERS			
Sterilizer Type	**Minimum Temperature**	**Full Cycle Time**	**Minimum Dry Time**
Gravity Displacement	132°C	15 minutes	See below

 **Wrap** 45 mins*	 **Wrap** 45 mins*
IFUSE TORQ INSTRUMENT SET, FLUORO (P/N 400451)	**IFUSE TORQ INSTRUMENT SET (P/N 400287)**

*After completion of the sterilization cycle in gravity displacement autoclaves, let the tray cool inside the autoclave with the door cracked for 30 minutes, or until it is not hot to the touch. If the tray is cool to the touch prior to 30 minutes, the tray may be removed and placed on a wire rack for the remainder of the 30-minute cooldown time. Ensure the tray is dry.

5. Substantial Equivalence Comparison

a. Predicate Device Identification

Table 5-1 identifies the predicate devices. The primary predicate device is the same as the subject device.

Table 5-1: Predicate Devices

Details	Subject Device	Primary Predicate	Secondary Predicate 1	Secondary Predicate 2
Device Name	iFuse Bedrock Granite Implant System	iFuse Bedrock Granite Implant System	CD Horizon Spinal System	ASTRA Spine System
Manufacturer	SI-BONE, Inc.	SI-BONE, Inc.	Medtronic Sofamor Danek	SpineCraft, LLC
510K	N/A	K222774 cleared on December 22, 2022	K223494 cleared on January 23, 2023	K223273 cleared on December 22, 2022
Device Classification	II	II	II	II
Classification Name	Smooth or threaded metallic bone fixation fastener Thoracolumbosacral Pedicle Screw System Stereotaxic instrument	Smooth or threaded metallic bone fixation fastener Thoracolumbosacral Pedicle Screw System Stereotaxic instrument	Thoracolumbosacral Pedicle Screw System	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3040 888.3070 882.4560	888.3040 888.3070 882.4560	888.3070 888.3060 888.3050	888.3070
Product Code	OUR NKB OLO	OUR NKB OLO	NKB KWP KWQ	NKB KWP KWQ
FDA Review Panel	Orthopedic	Orthopedic	Orthopedic	Orthopedic

b. Comparison of Indications for Use:

Both the subject device and the primary predicate device have the same intended use for sacroiliac joint fusion and augmenting immobilization and stabilization. The proposed indications for use statement of the subject device is different from the primary predicate device; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicates.

The proposed indications for use statement for the iFuse Bedrock Granite Implant System was amended with language describing use of the subject device in the pediatric population, similar to the secondary predicate devices.

Table 5-2 summarizes the proposed indication statement for the subject device and the previously cleared indication statements for the primary predicate and additional predicate devices. Note that

(b)(4)

(b)(4) The updates to the indications for use of the subject device do not alter the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Therefore, there are no questions raised on safety and effectiveness.

Table 5-2: Comparison of Indications for Use

(b)(4)

(b)(4)

(b)(4)

Based on similarities of the subject device to secondary predicates, the following warnings and precautions were added to the subject device's IFU:

Additional Warnings for Pediatric Patients
The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury.

Additional Precautions for Pediatric Patients
The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Risks related to use in pediatric patients are already covered by risks listed in the IFU.

c. Comparison of Technological Characteristics including Features and Materials

The subject device is the primary predicate. There are no changes in the subject device compared to the cleared primary predicate except for the new size offerings. The current iFuse Bedrock Granite Implant is manufactured in diameters between Ø10.5 mm – Ø13.5 mm and in lengths to accommodate the threaded screw post length range of 45 mm -120 mm. The proposed iFuse Bedrock Granite Implant will be manufactured with a diameter of Ø9.5 mm and available in lengths of 40 mm to 120 mm (in 5mm increments), thus introducing a new lower limit for diameter and length. The slightly smaller size for the subject device allows it to be placed into smaller anatomical corridors compared to the previously cleared primary predicate device.

The subject device is very similar to the predicates as follows:

- Design: the subject device and the primary predicate are threaded implants (screws) with a porous fusion sleeve; the secondary predicates are threaded implants (screws).
- Diameter: the subject device includes a smaller diameter of 9.5 mm when compared to the previously cleared primary predicate (Ø10.5 mm – Ø13.5 mm) but lies within the range of diameters offered by the secondary predicates.
- Implant lengths: the subject device includes a smaller length option of 40 mm as a line extension to the range offered by the previously cleared primary predicate (45-120 mm). The implant length lies within the range offered by the secondary predicates.
- Surface design: the subject device's surface has a porous and fenestrated surface design similar to the primary predicate.
- Manufacturing: the subject device and the primary predicate have an implant post that is traditionally machined and a sleeve that is additively manufactured and traditionally machined.

(b)(4)

(b)(4)

There are negligible differences in the technological characteristics between the subject device and the primary predicate device other than 1) the slightly smaller diameter (9.5 mm vs. 10.5 mm) and new lower limit for length (40 mm vs. 45 mm) and 2) minor modifications to the lattice surface of the implant. (b)(4)

(b)(4)

(b)(4) The smaller size also enables placement of the subject device in the S1 trajectory. This trajectory is common to pedicle screw systems including the two secondary predicate systems. Therefore, the overlap in size and technological characteristics between the subject device and the secondary predicates similarly do not raise different questions regarding safety and effectiveness.

d. Substantial Equivalence Comparison in Tabular Format

The subject device and primary predicate have the same intended use. The requested changes in this submission include the following:

1. Line extension of the implant: A new lower limit for the implant diameter and length (Ø9.5 mm and 40 mm respectively) has been included to the iFuse Bedrock Granite Implant System.

2. IFU updates: Expanded indications for use to include pediatric population and addition warnings and precautions related to pediatric use.

3. (b)(4)

(b)(4) This change will be reflected in the directions of use in the Surgical Technique Manual. (b)(4)

(b)(4)

The comparison of the indications for use and technological characteristics of the subject device and the predicates is provided in **Table 5-3** and most of the equivalence criteria are listed as the "same". The subject device is the primary predicate and the current implant is manufactured within the range of diameters between Ø10.5 mm – Ø13.5 mm and lengths between 45 mm -120 mm to accommodate the threaded screw post.

The proposed iFuse Bedrock Granite Implant will have a diameter of Ø9.5 mm and available in lengths of 40 mm to 120 mm (in 5mm increments), thus introducing a new lower limit for diameter and length. The line extension will allow the implant to be placed in smaller anatomical corridors compared to the previously cleared primary predicate device. The indication statement for use of the iFuse Bedrock Granite Implant System is also proposed to be expanded to include pediatric population, similar to the secondary predicate devices.

Comparison of the subject and predicate devices' technological characteristics did not identify different questions of safety or effectiveness. Testing to support this change is discussed in the Performance Testing section.

Table 5-3: Substantial Equivalence Comparison in Tabular Format

Equivalence Criteria	Subject Device: SI-BONE, Inc. iFuse Bedrock Granite Implant System	Primary Predicate: SI-BONE Inc. iFuse Bedrock Granite Implant System K222774	Secondary Predicate: Medtronic CD Horizon Spinal System K223494	Tertiary Predicate: SpineCraft ASTRA Spine System K223273	Conclusion
Regulatory Elements					
Device Classification	II	II	II		SAME
Classification Name	Smooth or threaded metallic bone fixation fastener Thoracolumbosacral Pedicle Screw System Stereotaxic instrument	Smooth or threaded metallic bone fixation fastener Thoracolumbosacral Pedicle Screw System Stereotaxic instrument	Thoracolumbosacral Pedicle Screw System	Thoracolumbosacral Pedicle Screw System	SAME as the primary predicate. Subsequent classification same as the secondary predicates.
Regulation Number	888.3040 888.3070 882.4560	888.3040 888.3070 882.4560	888.3070 888.3060 888.3050	888.3070	SAME as the primary predicate. Subsequent regulation same as the other predicates.
Product Code	OUR NKB OLO	OUR NKB OLO	NKB KWP KWQ	NKB KWP KWQ	SAME as the primary predicate. Subsequent product code same as the other predicates.
FDA Review Panel	Orthopedic	Orthopedic	Orthopedic	Orthopedic	SAME
Intended Use and Indications for Use					
Intended Use	Intended for sacroiliac joint fusion, and to augment immobilization and stabilization during thoracolumbar spine fusion	Intended for sacroiliac joint fusion, and to augment immobilization and stabilization during thoracolumbar spine fusion	Intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, or sacral spine	Intended to provide immobilization and stabilization in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine	SAME intended use as the primary predicate. Secondary and tertiary predicates' intended use is included in the subject device intended use.
Indications for Use	(b)(4)	The iFuse Bedrock Granite® Implant System is intended for sacroiliac joint fusion for the following conditions:	The CD Horizon™ Spinal System with or without Sextant™ instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following	The ASTRA Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the	Except for the expanded use in pediatric population, SAME indication statement as the primary predicate The subject device's indications for use is being expanded to

Equivalence Criteria	Subject Device: SI-BONE, Inc. iFuse Bedrock Granite Implant System	Primary Predicate: SI-BONE Inc. iFuse Bedrock Granite Implant System K222774	Secondary Predicate: Medtronic CD Horizon Spinal System K223494	Tertiary Predicate: SpineCraft ASTRA Spine System K223273	Conclusion
	(b)(4)	• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months • To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. • Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint When connected to compatible pedicle screw systems with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys the iFuse Bedrock Granite Implant System is intended to provide immobilization	indications: degenerative disc disease (DDD - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion. Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion. With the exception of DDD, the CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD Horizon™ Spinal System titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal	treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. The ASTRA Spine System is indicated for non-cervical (T1-S2/Ilium) pedicle fixation and non-pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; trauma (i.e., fracture and/or dislocation); spinal stenosis; deformities (scoliosis, lordosis and/or kyphosis); spinal tumor; and failed previous fusion (pseudo-arthrosis). When used in a percutaneous, posterior approach with AVANT Spine MIS instrumentation, the ASTRA Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease	include pediatric population similar to the secondary predicate devices.

Equivalence Criteria	Subject Device: SI-BONE, Inc. iFuse Bedrock Granite Implant System	Primary Predicate: SI-BONE Inc. iFuse Bedrock Granite Implant System K222774	Secondary Predicate: Medtronic CD Horizon Spinal System K223494	Tertiary Predicate: SpineCraft ASTRA Spine System K223273	Conclusion
	(b)(4)	and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: • Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies • Spondylolisthesis • Trauma (i.e., fracture or dislocation) • Spinal stenosis • Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis) • Spinal tumor • Pseudarthrosis • Failed previous fusion	deformities (i.e.scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. The CD Horizon™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cagefor patients diagnosed with DDD. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. The device is intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use. The CD Horizon™ Spire™ plate is a posterior, single-level,	(DDD - defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudo-arthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ASTRA Spine System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the ASTRA Spine System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are intended to be used with autograft and/or allograft.	

Equivalence Criteria	Subject Device: SI-BONE, Inc. iFuse Bedrock Granite Implant System	Primary Predicate: SI-BONE Inc. iFuse Bedrock Granite Implant System K222774	Secondary Predicate: Medtronic CD Horizon Spinal System K223494	Tertiary Predicate: SpineCraft ASTRA Spine System K223273	Conclusion
	(b)(4)	Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods. The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data-based model of the anatomy. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.	non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD (as previously defined), spondylolisthesis, trauma, and/or tumor. In order to achieve additional levels of fixation, the CD Horizon™ Spinal System rods may be connected to the Vertex™ Reconstruction System with the Vertex™ rod connector. Refer to the Vertex™ Reconstruction System package insert for a listof the Vertex™ indications of use.	Pediatric pedicle screw fixation is limited to a posterior approach. The ASTRA fenestrated screw when used with other components of the ASTRA Spine System is indicated to provide the surgeon with an open or minimally invasive approach for posterior spinal surgery. The ASTRA fenestrated screw is intended to be used with saline or radiopaque dye.	

Equivalence Criteria	Subject Device: SI-BONE, Inc. iFuse Bedrock Granite Implant System	Primary Predicate: SI-BONE Inc. iFuse Bedrock Granite Implant System K222774	Secondary Predicate: Medtronic CD Horizon Spinal System K223494	Tertiary Predicate: SpineCraft ASTRA Spine System K223273	Conclusion
	(b)(4)				
Pediatric specific warnings and precautions	**Additional Warnings for Pediatric Patients** The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. **Additional Precautions for Pediatric Patients** The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.	N/A	**Additional Warnings for Pediatric Patient** Warning: the safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine. Other adverse events related to	Use of this type of surgical implant surgery in children or pediatric patients presents particular risks because of bone growth or physical movement. Subsequent re-intervention may be required.	The subject device's indications for use are being expanded to include pediatric population. The subject device's IFU was augmented with warnings and precautions related to pediatric use similar to those listed in the secondary devices' IFUs.

Equivalence Criteria	Subject Device: SI-BONE, Inc. iFuse Bedrock Granite Implant System	Primary Predicate: SI-BONE Inc. iFuse Bedrock Granite Implant System K222774	Secondary Predicate: Medtronic CD Horizon Spinal System K223494	Tertiary Predicate: SpineCraft ASTRA Spine System K223273	Conclusion
			pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their smaller stature. **Additional Precautions for Pediatric Patients** The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients. The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients. Physician note: although the physician is the learned intermediary between the company and the patient,		

Equivalence Criteria	Subject Device: SI-BONE, Inc. iFuse Bedrock Granite Implant System	Primary Predicate: SI-BONE Inc. iFuse Bedrock Granite Implant System K222774	Secondary Predicate: Medtronic CD Horizon Spinal System K223494	Tertiary Predicate: SpineCraft ASTRA Spine System K223273	Conclusion
			the important medical information given in this document should be conveyed to the patient.		
User and Trajectories					
User	Qualified surgeons	Qualified surgeons	Qualified surgeons	Qualified surgeons	SAME
Trajectory	S1, SAI or iliac trajectories	SAI or iliac trajectories	S1, SAI or iliac trajectories	S1, SAI or iliac trajectories	Similar to primary predicate and S1 added. The subject device's trajectories are reflected in the secondary predicate trajectories.
Design and Technological Features					
Single use/Reusable Device	Implant – Single Use Instruments – Reusable and Disposable Instruments	Implant – Single Use Instruments – Reusable and Disposable Instruments	Implant – Single Use Instruments – Reusable and Disposable Instruments	Implant – Single Use Instruments – Reusable and Disposable Instruments	SAME
Implant Outer Diameter	9.5 mm	10.5-13.5 mm	4.0-10.5 mm 5.5-8.5 mm (pelvic fixation implants)	4.5-7.0 mm (uniplanar screws) 4.5-9.5 mm (polyaxial screws)	Similar size range to the predicates and line extension to the primary predicate
Implant Lengths	40-120 mm	45-120 mm	20-100mm	25–50 mm (uniplanar screws) 25–100 mm (polyaxial screws)	Similar size range to the predicates and line extension to the primary predicate
Implant Threads	Dual-single-dual lead threads	Dual-single-dual lead threads	Dual lead threads	Double lead threads	SAME as primary predicate
External Surface features	Porous, fenestrated	Porous, fenestrated	Smooth, fenestrated	Smooth	Similar to the primary predicate
Guidewire Compatibility	Yes (Ø 1.6 mm)	Yes (Ø 1.6 mm)	Yes	Not described in the surgical manual	SAME as primary predicate
Instruments	Instrument set for placement and removal	Instrument set for placement and removal	Instrument set for placement and removal	Instrument set for placement and removal	SAME
Materials and Manufacturing					

Equivalence Criteria	Subject Device: SI-BONE, Inc. iFuse Bedrock Granite Implant System	Primary Predicate: SI-BONE Inc. iFuse Bedrock Granite Implant System K222774	Secondary Predicate: Medtronic CD Horizon Spinal System K223494	Tertiary Predicate: SpineCraft ASTRA Spine System K223273	Conclusion
Materials	Post: Ti-6Al-4V ELI per ASTM F136 Sleeve: Ti-6Al-4V ELI per ASTM F3001	Post: Ti-6Al-4V ELI per ASTM F136 Sleeve: Ti-6Al-4V ELI per ASTM F3001	Titanium alloy per ASTM F136, CoCr alloy per ASTM F1537 and Titanium per ASTM F67	Titanium alloy per ASTM F136 and CoCr alloy per ASTM F1537	SAME (Titanium Alloy)
Biocompatibility EN ISO 10993-1	Implant with permanent >30 day Instruments with limited < 24 hour	Implant with permanent >30 day Instruments with limited < 24 hour	Implant with permanent >30 day Instruments with limited < 24 hour	Implant with permanent >30 day Instruments with limited < 24 hour	SAME
Manufacturing	Post: traditionally machined Sleeve: additively manufactured and traditionally machined	Post: traditionally machined Sleeve: additively manufactured and traditionally machined	Traditionally machined	Traditionally machined	SAME as the primary predicate
Sterilization Method (implant)	Supplied sterile via gamma irradiation; SAL 10^{-6} Steam sterilization	Supplied sterile via gamma irradiation; SAL 10^{-6} Steam sterilization	Steam sterilization	Steam sterilization	SAME as the primary predicate

e. Substantial Equivalence Conclusion

The iFuse Bedrock Granite Implant System is substantially equivalent to its predicates in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation as the predicate devices: the SI-BONE iFuse Bedrock Granite Implant System (most recently cleared in K222774), Medtronic CD Horizon Spinal System (most recently cleared in K223494) and the SpineCraft ASTRA Spine System (most recently cleared in K223273). Any differences between the iFuse Bedrock Granite Implant System and the predicate devices do not raise different questions of safety or effectiveness and do not alter the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, as demonstrated by the results of the verification and validation testing. Therefore, it can be concluded that the iFuse Bedrock Granite Implant System is substantially equivalent to the predicate devices.

3C.1 Description of Device Packaging

Except for (b)(4) there are no changes made to the device packaging as part of this 510(k). The remainder of this section is provided for completeness.

(b)(4)

Figure 3C-1. Fully Integrated Implant in packaging (exploded view)

The iFuse Bedrock Granite Implants are packaged using the following packaging components (refer to **Table 3C-1** below).

Table 3C-1. iFuse Bedrock Granite Implant Packaging Components and Parts

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EXECUTIVE SUMMARY

The iFuse Bedrock Granite implant is a sterile, single-use implant that combines features of a porous fusion device with the threaded length and posterior rod connection features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the Iliac trajectories. It is designed for connection to commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm titanium alloy or cobalt chrome alloys spinal fixation rods.

SI-Bone, Inc. is submitting this Traditional 510(k) to include the following changes to the iFuse Bedrock Granite Implant:

1. Line extension of the implant: A new lower limit for both diameter and length (Ø9.5 mm and 40 mm respectively) has been included to the iFuse Bedrock Granite Implant System. These (b)(4)

2. IFU updates for Pediatric Indication: Expanded indications for use to include pediatric population and addition of warnings and precautions specific to pediatric population.

(b)(4)

The current iFuse Bedrock Granite implant is manufactured within the range of diameters between Ø10.5 mm – Ø13.5 mm and lengths between 45 mm -120 mm to accommodate the threaded screw post. The proposed iFuse Bedrock Granite Implant will have a slightly smaller diameter (Ø9.5 mm) and and be provided in lengths of 40 mm to 120 mm (in 5mm increments) thus introducing a new lower limit for diameter and length. The new size offering will allow the implant to be placed in smaller anatomical corridors compared to the previously cleared primary predicate device. Note that there are no new or unique instruments required for implantation of the subject 9.5 mm iFuse Bedrock Granite Implant. The same Open (P/N 400309) and MIS (P/N 400310) Instrument Sets cleared under K220195 are also utilized for placing the subject 9.5 mm Granite Implant.

The indications for use of the iFuse Bedrock Granite Implant System are also proposed to be expanded to include pediatric population similar to the secondary predicate devices.

Table 14-1 identifies the predicate devices for the iFuse Bedrock Granite Implant. The primary predicate device is the same as the subject device.

Table 14-1: Predicate Devices

Details	Subject Device	Primary Predicate	Secondary Predicate 1	Secondary Predicate 2
Device Name	iFuse Bedrock Granite Implant System	iFuse Bedrock Granite Implant System	CD Horizon Spinal System	ASTRA Spine System
Manufacturer	SI-BONE, Inc.	SI-BONE, Inc.	Medtronic Sofamor Danek	SpineCraft, LLC
510K	N/A	K222774 cleared on December 22, 2022	K223494 cleared on January 23, 2023	K223273 cleared on December 22, 2022
Device Classification	II	II	II	II
Classification Name	Smooth or threaded metallic bone fixation fastener Thoracolumbosacral Pedicle Screw System Stereotaxic instrument	Smooth or threaded metallic bone fixation fastener Thoracolumbosacral Pedicle Screw System Stereotaxic instrument	Thoracolumbosacral Pedicle Screw System	Thoracolumbosacral Pedicle Screw System
Regulation Number	888.3040 888.3070 882.4560	888.3040 888.3070 882.4560	888.3070 888.3060 888.3050	888.3070
Product Code	OUR NKB OLO	OUR NKB OLO	NKB KWP KWQ	NKB KWP KWQ
FDA Review Panel	Orthopedic	Orthopedic	Orthopedic	Orthopedic

The comparison of the indications for use and technological characteristics of the subject device and the predicates is provided in Attachment 5_Substantial Equivalence Comparison' and most of the equivalence criteria are listed as the "same". Comparison of the subject and predicate devices' technological characteristics did not identify different questions of safety or effectiveness.

The product label for the line extension of the implant, updated IFU and STM are provided in the Attachment 6 Labeling Overview. There is no impact to biocompatibility, sterilization or shelf life of the iFuse Bedrock Granite Implants as a result of this line extension. Performance testing for the subject device was performed (b)(4) (b)(4) and the safety and performance of the subject device for its intended use was demonstrated.

The iFuse Bedrock Granite Implant System is substantially equivalent to its predicates in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. Any differences between the iFuse Bedrock Granite Implant System and the predicate devices do not raise different questions of safety or effectiveness and do not alter the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, as demonstrated by the

results of the verification and validation testing. Therefore, it can be concluded that the iFuse Bedrock Granite Implant System is substantially equivalent to the predicate devices.

7 Reprocessing and Sterility

7.1 Description of Device Packaging to Maintain Sterility

Except for (b)(4) there are no changes made to the device packaging as part of this 510(k). The remainder of this section is provided for completeness.

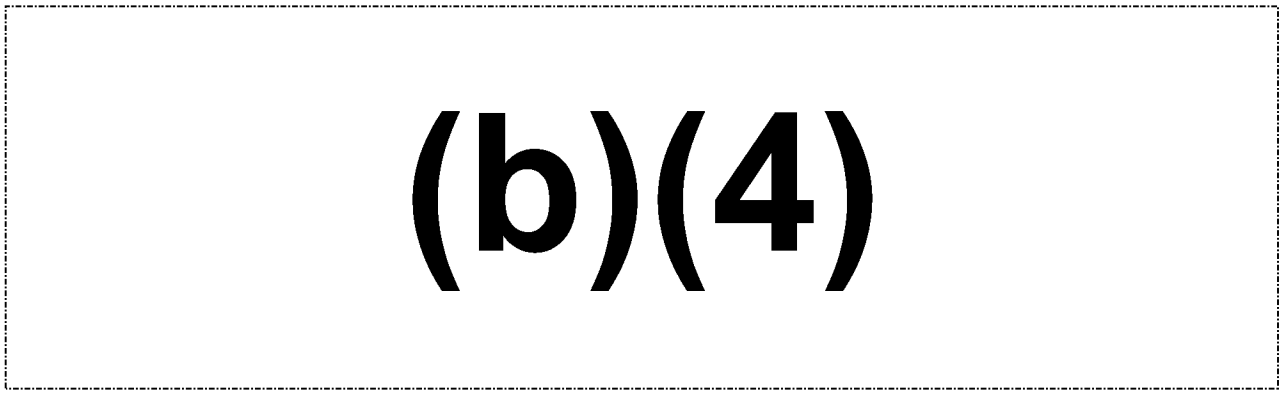
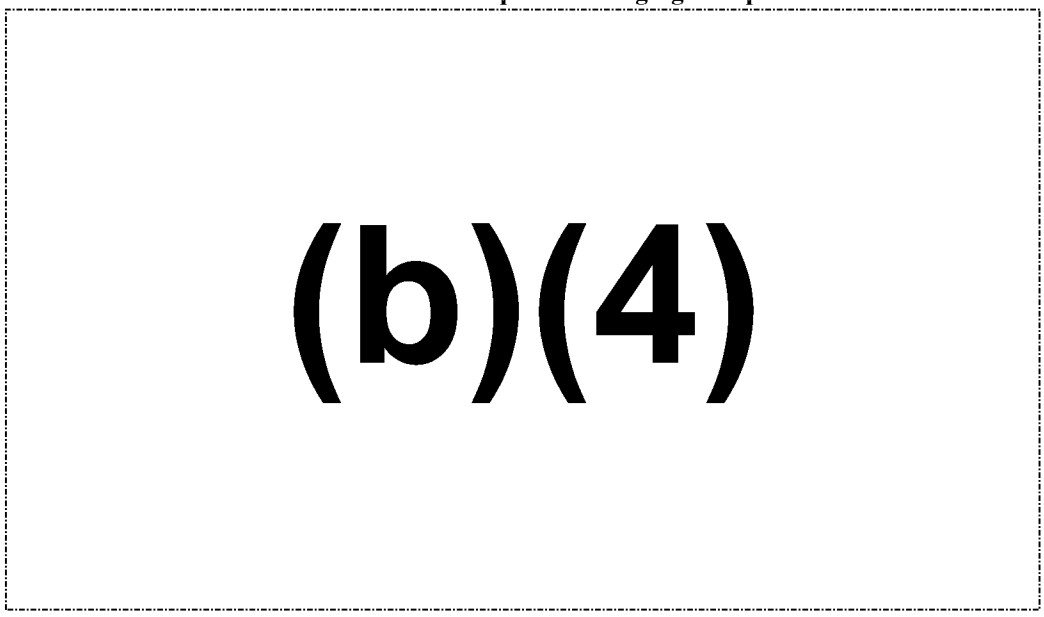
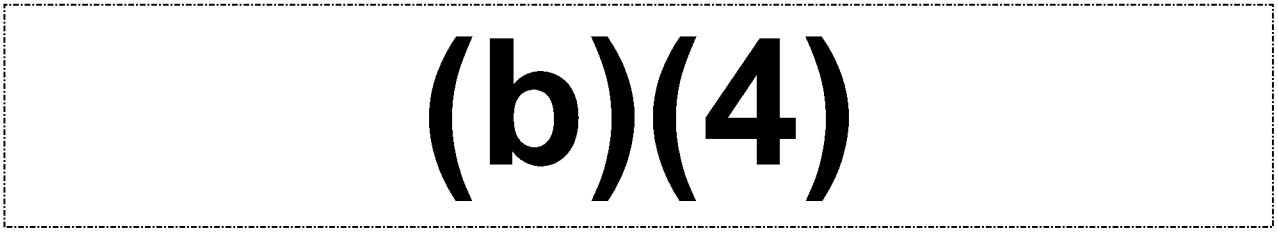


Figure 7-1. Fully Integrated Implant in packaging (exploded view)

The iFuse Bedrock Granite Implants are packaged using the following packaging components (refer to **Table 7-1** below).

Table 7-1. iFuse Bedrock Granite Implant Packaging Components and Parts





(b)(4)

Packaging Validation to Maintain Sterile Barrier

As described in K220195, packaging validation testing was performed by SI-BONE using worst-case configuration which included a 13.5 mm x 120 mm iFuse Bedrock Granite Implant as it has the greatest length, diameter and thus mass. The results of the packaging validation testing are applicable for the subject device (reduced implant diameter and length).

A total of 60 test units were subjected to environmental conditioning per ASTM D4332-14, simulated transportation per ASTM D4169-16 (Distribution Cycle 13) and packaging integrity testing per ASTM D3078 in accordance with EN ISO 11607-1:2019 - *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*, to ensure that the packaging and devices will not be compromised during shipping (**Table 7-2**).

Table 7-2: Transportation / Packaging Validation for iFuse Bedrock Granite Implants

Test Input	Standard Referenced	ASTM Schedule	Assurance Level
Initial Manual Handling	ASTM D5276-19	A	II
Vehicle Stacking	ASTM D642-15	C	II
Loose Load Vibration	ASTM D999-08 (2015)	F	II
Low Pressure (High Altitude) Hazard	ASTM D6653	I	n/a
Vehicle Vibration	ASTM D4728-17	E	II
Final Manual Handling	ASTM D5276-19	A	II
Visual Inspection of Packaging	n/a - performed per SI-BONE Test Protocol 300979-P	n/a	n/a
Sterile Barrier Testing	ASTM D3078-02 (2021)	n/a	n/a
Visual Inspection of Product and Labeling	n/a- performed per SI-BONE Test Protocol 300979-P	n/a	n/a

(b)(4)

The results of the packaging validation testing demonstrated that the packaging components for the iFuse Bedrock Granite Implant support transportation and adequately protect the iFuse Bedrock Granite Implants and associated components with no observations.

7.2 iFuse Bedrock Granite Implants

a. Cleaning

(b)(4)

Table 7-4 shows the sterilization process impact comparison between the subject and primary predicate devices.

Table 7-4 Sterilization Process Impact - Comparison between the Primary Predicate and Subject Device

(b)(4)

(b)(4)

(b)(4) the subject devices remain compliant with the cleaning validation requirements per EN ISO 19227:2018 *Implants for Surgery – Cleanliness of Orthopedic Implants – General Requirements.* Implants are final cleaned, assembled and packaged at QTS.

b. Sterilization Method for Devices Provided Sterile

iFuse Bedrock Granite implants are sterilized using methods (b)(4) Each lot of iFuse Bedrock Granite implants is sterilized by gamma irradiation using a minimum dose of (b)(4) to ensure a Sterility Assurance Level (SAL) of 10^{-6}. The validated sterilization dose is between (b)(4) (b)(4)

c. Sterilization Facility

(b)(4)

d. Description of Sterilization Validation Method

(b)(4)

The sterilization process has been validated in accordance with the applicable sections of the following standards:

- SS EN ISO 11137-1:2015 - *Sterilization of Health Care Products: Radiation Sterilization - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices*
- SS EN ISO 11137-2:2015 - *Sterilization of Health Care Products: Radiation Sterilization - Part 2: Establishing the Sterilization Dose – Method VD-Max 25*

Sterilization validation substantiated that a minimum (b)(4) production dose provides a Sterility Assurance Level of 10^{-6}. The validated production dose is (b)(4)

(b)(4)

The gamma irradiation sterilization validation covers the iFuse Bedrock Granite Implants. Based on successful completion of the tests performed, the gamma sterilization process for the iFuse Bedrock Granite Implant is considered validated.

e. Sterility Assurance Level (SAL)

The sterilization process has been validated to a Sterility Assurance Level (SAL) of 10^{-6}. SAL is (b)(4)

f. Pyrogenicity

(b)(4)

7.3 Reusable End Sterilized or Disinfected Devices

(b)(4)

a. Cleaning Method and Cleaning Validation

The cleaning method for iFuse Bedrock Granite instruments (b)(4) The cleaning instructions are provided for reference for each device and/or accessory, as applicable in **Attachment 6D**.

b. Sterilization Method

The sterilization processes for the iFuse Bedrock Granite Instrument Sets (b)(4) (b)(4) The sterilization and cleaning instructions for the instruments and accessories are provided **Attachment 6D** for reference.

c. Sterilization Facility

(b)(4)

d. Description of the Sterilization Validation Method

The sterilization validation method (b)(4) SI-BONE has conducted steam sterilization validation in accordance with ANSI /AAMI / ISO 17665-1, Annex D to achieve a SAL of 10^{-6}. The Steam Sterilization Validation Protocol and Report (b)(4) are available on file at SI-BONE. Based on the successful completion of tests performed, the steam sterilization process for the iFuse Bedrock Granite Instrument Sets is considered validated.

e. Sterility Assurance Level (SAL)

SAL (b)(4) The sterilization process has been validated to a Sterility Assurance Level (SAL) of 10^{-6}.

f. Pyrogenicity

(b)(4)

g. Device types listed in the Federal Register (FR)

Not Applicable, (b)(4)

(b)(4)

h. Device Specific Guidance for Sterility and/or Reprocessing

Not Applicable. (b)(4)

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

iFuse Bedrock Granite Implant Model Numbers

Description	Part Number P/N
Open Head Tulip	
9.5 mm X 40 mm iFuse Bedrock Granite Implant	095040BG
9.5 mm X 45 mm iFuse Bedrock Granite Implant	095045BG
9.5 mm X 50 mm iFuse Bedrock Granite Implant	095050BG
9.5 mm X 55 mm iFuse Bedrock Granite Implant	095055BG
9.5 mm X 60 mm iFuse Bedrock Granite Implant	095060BG
9.5 mm X 65 mm iFuse Bedrock Granite Implant	095065BG
9.5 mm X 70 mm iFuse Bedrock Granite Implant	095070BG
9.5 mm X 75 mm iFuse Bedrock Granite Implant	095075BG
9.5 mm X 80 mm iFuse Bedrock Granite Implant	095080BG
9.5 mm X 85 mm iFuse Bedrock Granite Implant	095085BG
9.5 mm X 90 mm iFuse Bedrock Granite Implant	095090BG
9.5 mm X 95 mm iFuse Bedrock Granite Implant	095095BG
9.5 mm X 100 mm iFuse Bedrock Granite Implant	095100BG
9.5 mm X 105 mm iFuse Bedrock Granite Implant	095105BG
9.5 mm X 110 mm iFuse Bedrock Granite Implant	095110BG
9.5 mm X 115 mm iFuse Bedrock Granite Implant	095115BG
9.5 mm X 120 mm iFuse Bedrock Granite Implant	095120BG
Closed Head Tulip	
9.5 mm X 40 mm iFuse Bedrock Granite Implant	095040CH
9.5 mm X 45 mm iFuse Bedrock Granite Implant	095045CH
9.5 mm X 50 mm iFuse Bedrock Granite Implant	095050CH
9.5 mm X 55 mm iFuse Bedrock Granite Implant	095055CH
9.5 mm X 60 mm iFuse Bedrock Granite Implant	095060CH
9.5 mm X 65 mm iFuse Bedrock Granite Implant	095065CH
9.5 mm X 70 mm iFuse Bedrock Granite Implant	095070CH
9.5 mm X 75 mm iFuse Bedrock Granite Implant	095075CH
9.5 mm X 80 mm iFuse Bedrock Granite Implant	095080CH
9.5 mm X 85 mm iFuse Bedrock Granite Implant	095085CH
9.5 mm X 90 mm iFuse Bedrock Granite Implant	095090CH
9.5 mm X 95 mm iFuse Bedrock Granite Implant	095095CH
9.5 mm X 100 mm iFuse Bedrock Granite Implant	095100CH
9.5 mm X 105 mm iFuse Bedrock Granite Implant	095105CH
9.5 mm X 110 mm iFuse Bedrock Granite Implant	095110CH
9.5 mm X 115 mm iFuse Bedrock Granite Implant	095115CH
9.5 mm X 120 mm iFuse Bedrock Granite Implant	095120CH

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SI-BONE

October 31, 2023

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

RE: Traditional 510(k) Premarket Notification
SI-BONE, Inc. iFuse Bedrock Granite

Attention: Mr. Colin O'Neill, M.S.
DHT6B Extracolumnar Spinal Devices
Division of Health Technology 6 B (Spinal Devices)
Office of Health Technology 6 (OHT 6: Orthopedic Devices)

Dear Mr. O'Neill and 510(k) Review Team,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") and 21 C.F.R. § 807, SI-BONE, Inc. ("SI-BONE") is submitting this Traditional 510(k) premarket notification for the iFuse Bedrock Granite Implant System, consisting of the iFuse Bedrock Granite Implant and associated instruments. This submission has been prepared in accordance with the recommendations made by the Agency in the FDA Guidance: *Format for Traditional and Abbreviated 510(k)s* issued on September 13, 2019, and is in accordance with the *Electronic Submission Template for Medical Device 510(k) Submissions* issued on October 2, 2023.

The subject device, iFuse Bedrock Granite Implant and associated instruments, (b)(4) (b)(4) (b)(4) Following that, the device was cleared as part of K222774 on December 22, 2022, to expand the indications for the subject device to include compatibility with 5.5- and 6.0 mm titanium alloy and cobalt chrome alloys Pedicle Screw Systems rods. The intended use of the subject device is sacroiliac (SI) joint fusion and pelvic fixation during thoracolumbar spine fusion surgeries.

The purpose of the current submission is to include the following changes to the iFuse bedrock Granite Implant:

1. Line extension of the implant: A new lower limit for diameter and length (Ø9.5 mm and 40 mm respectively) has been included to the iFuse Bedrock Granite Implant System.

2. IFU updates for Pediatric Indication: Expanded indications for use to include pediatric population and addition of warnings and precautions specific to pediatric population.

3. (b)(4)

4. (b)(4)

The subject device is slightly smaller in diameter (Ø 9.5 mm vs. Ø10.5 mm – Ø13.5 mm for the primary predicate) and slightly shorter (smallest length 40 mm vs. 45-120 mm for the primary predicate). The smaller dimensions introduce a new lower limit for diameter and length. The new size offering will allow the implant to be placed in smaller anatomical corridors compared to the previously cleared primary predicate device. The indications for use of the iFuse Bedrock Granite Implant System are also proposed to be expanded to include pediatric population similar to the secondary predicate devices. (b)(4)
(b)(4)

This 510(k) describes the performance testing conducted to support the reduced size offering of the implant. The testing did not raise different questions of safety and effectiveness compared to the predicate device. Therefore, test results support adequate expected performance of the line extension as well as substantial equivalence between the subject device and its cleared predicate.

We request that the Food and Drug Administration hold confidential the information of our intent to seek 510(k) clearance for the subject device and the information provided in this submission, pursuant to 21 CFR 807.95.

We thank the Agency for its review of this application. I am available for any questions using the below contact information.

Sincerely,

Digitally Signed by:
(b)(6)

Jayasri Prabakaran
Associate Director of Regulatory Affairs
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471 El Camino Real, Suite 101
Santa Clara, CA 95050
Mobile: (b)(6)
Email: Jayasri.Prabakaran@si-bone.com

3 Device Description

3.1 Device Specific Guidance

The device description section is written in accordance with the applicable parts of Spinal System 510(k)s Guidance Document, dated 2004.

3.2 iFuse Bedrock Granite Implant System

3.2.1 General Device Description

The iFuse Bedrock Granite Implant System consists of implants of various lengths and diameters, and associated instrument sets for both open and minimally invasive (MIS) approaches. The titanium (Ti-6Al-4V ELI) implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the Iliac trajectories. It is designed for connection to commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm titanium alloy or cobalt chrome alloys spinal fixation rods.

The subject device is slightly smaller in diameter (9.5 mm) and is provided in lengths slightly shorter (40 mm). The surface of the sleeve is also slightly different (see below). Otherwise, the subject device is identical to previously cleared iFuse Bedrock Granite implants.

(b)(4)

Note that there are no new or unique instruments required for implantation of the subject 9.5 mm iFuse Bedrock Granite Implant. The same Open (P/N 400309) and MIS (P/N 400310) Instrument Sets cleared (b)(4) are also utilized for the subject 9.5 mm Granite Implant.

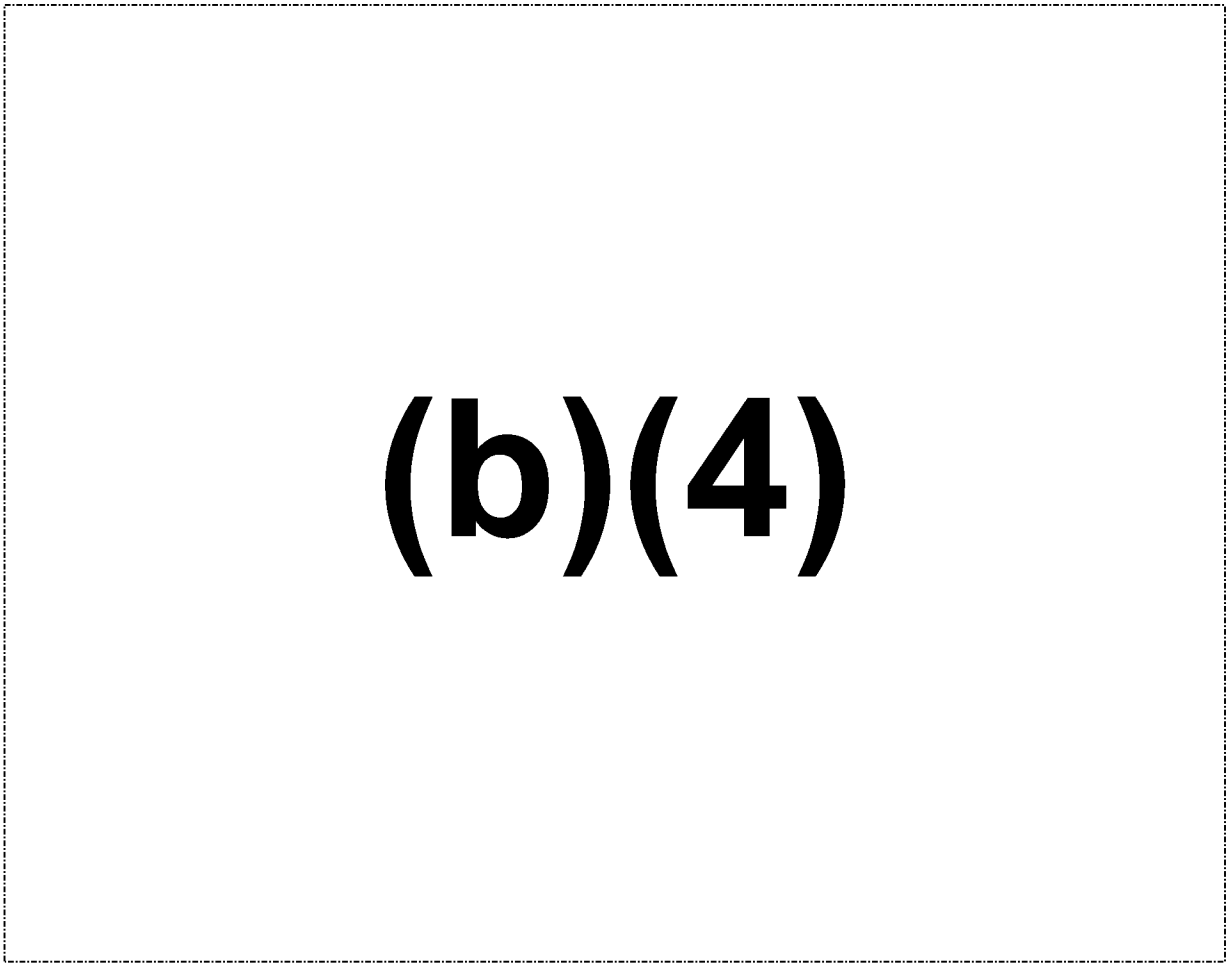
3.2.2 iFuse Bedrock Granite Implant: Detailed Description

The iFuse Bedrock Granite implant is a sterile, single-use implant that combines features of a porous fusion device with the threaded length and posterior rod connection features of a typical pedicle fixation screw.

(b)(4) Information in the sections below is provided for references purposes. Key features are shown in **Table 3-1**. Engineering drawings are provided in **Attachment 3B**.

Table 3-1. **Key design features and associated purposes of iFuse Bedrock Granite Implant**

(b)(4)



3.2.2.1 iFuse Bedrock Granite Implant Detailed Description

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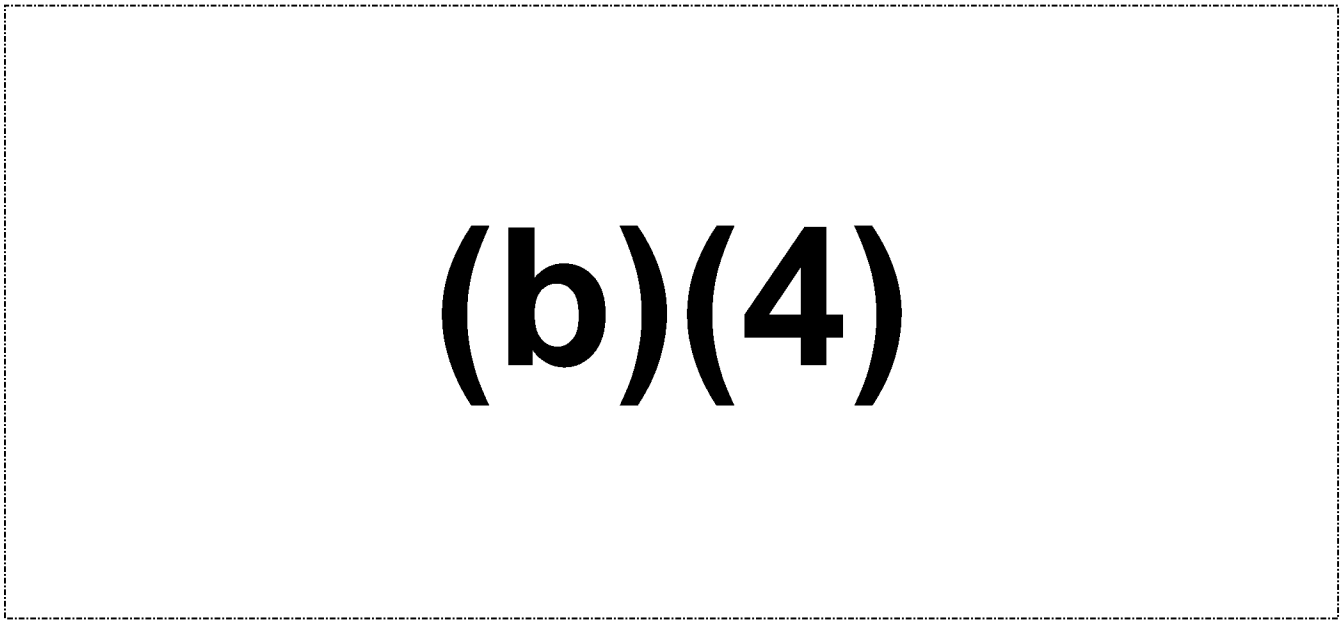
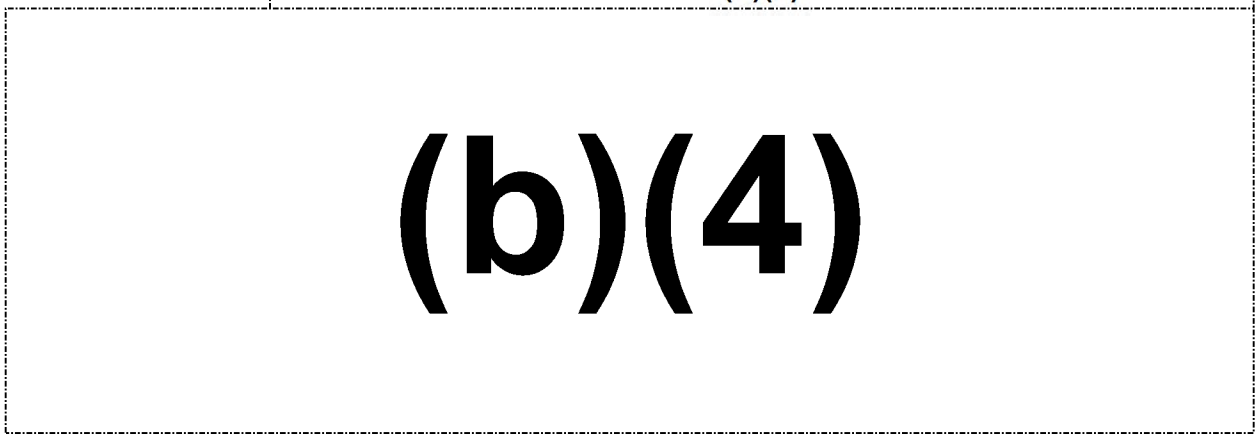
(b)(4)

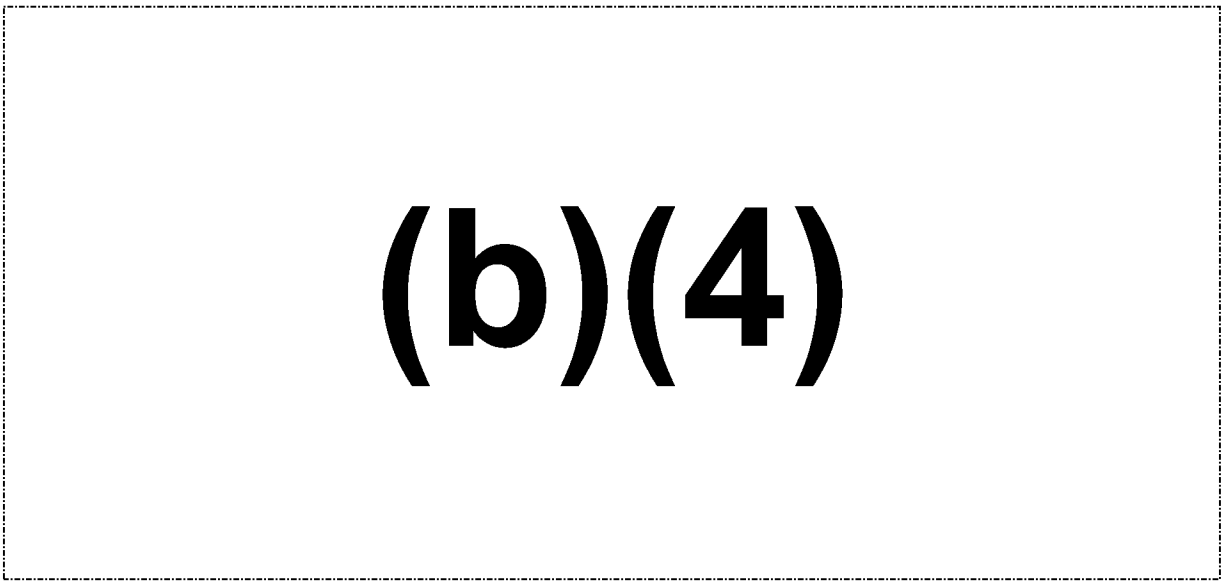
(b)(4)



3.2.2.2 9.5 mm iFuse Bedrock Granite Fusion Sleeve

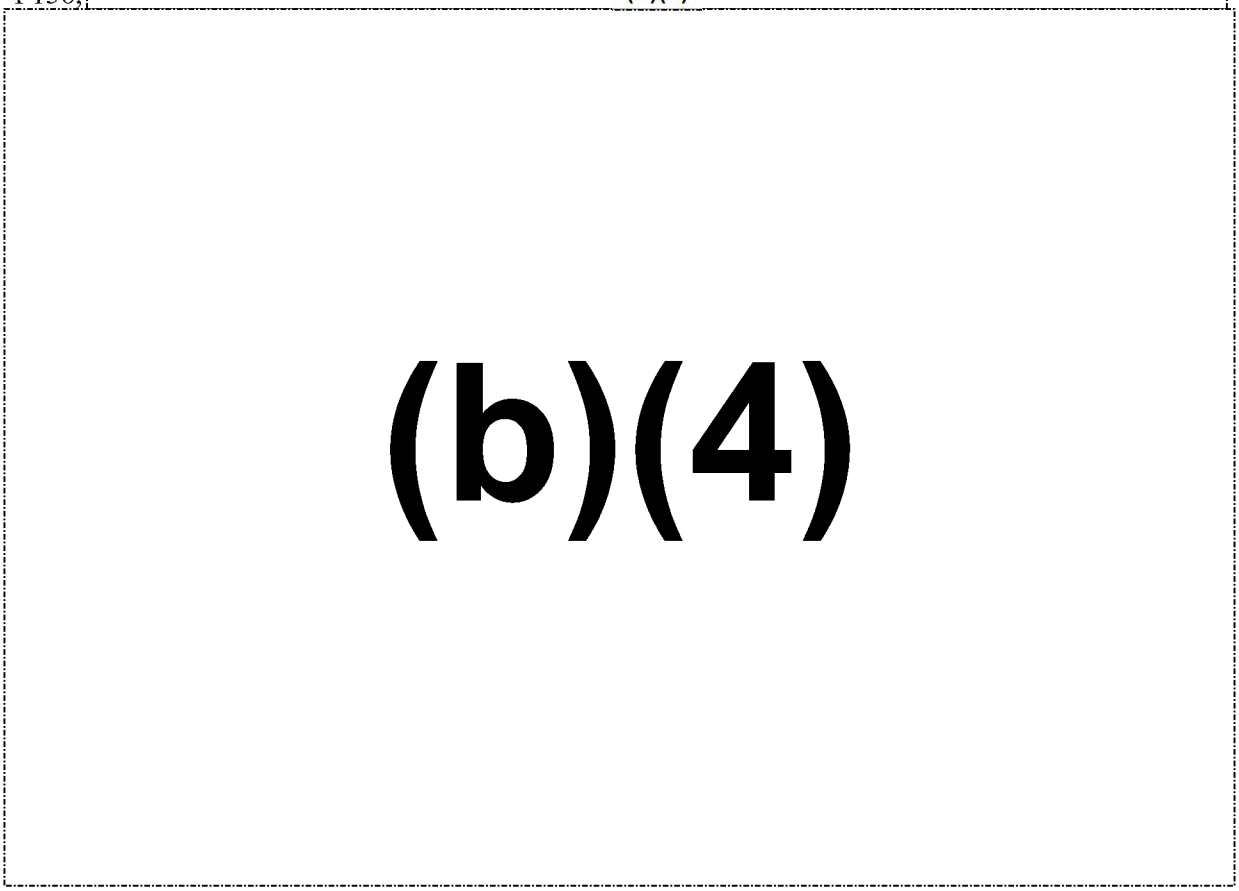
The iFuse Bedrock Granite Implant fusion sleeve is an additively manufactured Ti-6Al-4V ELI per ASTM F3001 sleeve (b)(4)





3.2.2.3 iFuse Bedrock Granite Implant Threaded Screw Post

The iFuse Bedrock Granite Implant threaded screw post is a machined Ti-6Al-4V ELI per ASTM F136, (b)(4)



3.2.2.4 iFuse Bedrock Granite Implant Tulip Connector

(b)(4)

3.2.2.5 iFuse Bedrock Granite Implant Set Screw and Rod Interface

(b)(4)

(b)(4)

(b)(4)

(b)(4)

2.2.7 Minor Design Differences between the Subject and Primary Predicate Devices

(b)(4)

(b)(4)

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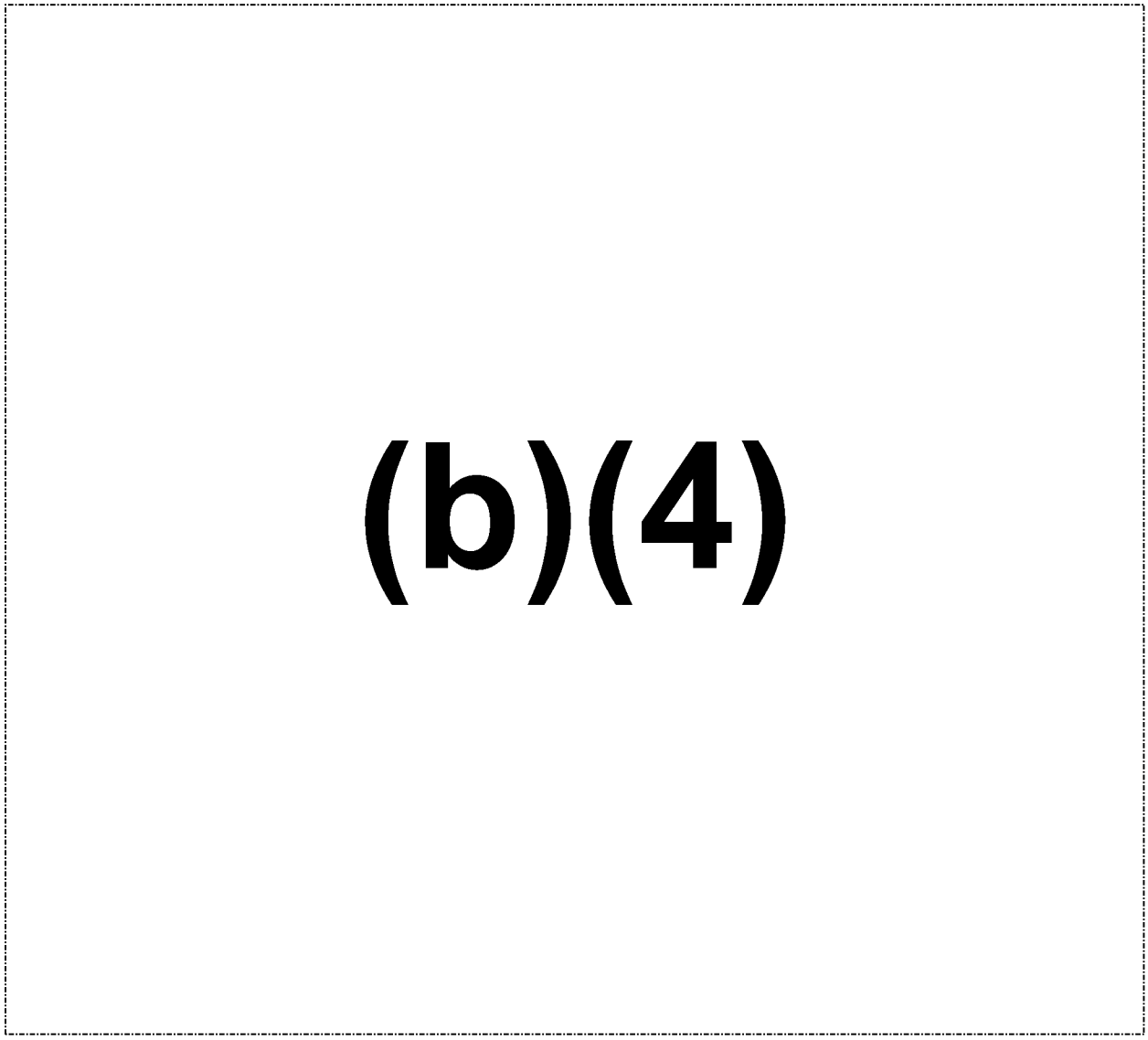
3.2.3 Additional Design Changes

(b)(4)



3.2.4 Principles of Operation

(b)(4). The iFuse Bedrock Granite Implant is intended to provide both fusion of the sacroiliac joint and fixation (i.e., permanent immobilization and stabilization) to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion.

3.2.5 Proposed Conditions of Use

But for one aspect, there are no changes to the proposed conditions for use for the subject device. The subject device is used by spine or neurosurgeons during thoracolumbar spine fusion surgery to aid in spinopelvic fixation and fusion of the SI joint.

SI-BONE proposes the following change. (b)(4) this 510k describes optional placement of the subject device in the S1 trajectory. This trajectory does not imply

any change to the intended use nor use steps of the subject device (i.e., placement within bone and attachment to posterior spinal rods). This trajectory is commonly used by surgeons performing thoracolumbar fusions. This change will be reflected in the directions of use in the Surgical Technique Manual.

12. Performance Testing Summary

(b)(4)

In the current submission, the subject device is a slightly smaller variation of the previously cleared set of implants. Performance testing for the subject device was performed (b)(4) (b)(4) (b)(4) The same product codes (OUR, NKB and OLO) apply to the subject device. As shown below, testing showed that design changes required to make the subject device slightly smaller do not raise different questions of safety and effectiveness, and the safety and performance of the subject device for its intended use was demonstrated. Further, the subject device's size is similar to that of other FDA-cleared pedicle screws and pelvic fixation screws.

SI-BONE identified and performed verification and/or validation activities required by 21 CFR 820.30 (Design Control), including describing the methods or tests used and the acceptance criteria applied. All testing was performed by qualified individuals or test laboratories to ensure the iFuse Bedrock Granite Implant System as a whole met the device performance and predetermined acceptance criteria. The bench performance testing performed for the iFuse Bedrock Granite Implant System is identical to the test methods utilized for the primary predicate device.

(b)(4)

Table 12-1: Testing not required for subject device

(b)(4)

(b)(4)

12.1 Summary of Performance Data

Design changes for the predicate device affect only a subset of verification and validation tests, which are described in **Table 12-2** and **Table 12-3**. Design verification and validation testing demonstrates that the proposed 9.5 mm diameter line extension of the iFuse Bedrock Granite Implant System is safe and effective for its intended clinical use and is substantially equivalent to the predicate devices.

Complete test protocols and reports are provided in **Attachment 12B**.

Table 12-2: Implant Performance Testing Related to OUR Product Code

Link to Ref	Test and Compliance	Sample and Sample Size	Acceptance Criteria	Results	PASS/ FAIL	Equivalence Conclusion
Static and Dynamic Cantilever (F2193) Testing Bedrock Granite, Test Protocol and Report (b)(4) (b)(4)	Static and Dynamic Cantilever Testing ASTM F2193	(b)(4)				
Torsion (ASTM F543) Testing Bedrock Granite, Test Protocol and Report (b)(4) (b)(4)	Static Torsion Testing ASTM F543					
Axial Pullout (ASTM F543) Testing Bedrock Granite Test Protocol and Report (b)(4) (b)(4)	Static Axial Pull-out Test ASTM F543					

Link to Ref	Test and Compliance	Sample and Sample Size	Acceptance Criteria	Results	PASS/ FAIL	Equivalence Conclusion
Characterizing the Porous Surface Bedrock Granite Test Protocol and Report (b)(4) (b)(4)	Static Shear Testing FDA Guidance for Metallic Coatings ASTM F1044-05 (2017)	(b)(4)				
Characterizing the Porous Surface Bedrock Granite Test Protocol and Report (b)(4) (b)(4)	Shear Fatigue Testing FDA Guidance for Metallic Coatings ASTM F1160-14 (2017) ISO 13179-1					
Characterizing the Porous Surface Bedrock Granite Test Protocol and Report (b)(4) (b)(4)	Static Tensile Testing FDA Guidance for Metallic Coatings ASTM F1147-05 (2017)					
Characterizing the Porous Surface Bedrock Granite Test Protocol and Report (b)(4) (b)(4)	Abrasion Properties					

Link to Ref	Test and Compliance	Sample and Sample Size	Acceptance Criteria	Results	PASS/ FAIL	Equivalence Conclusion
	FDA Guidance for Metallic Coatings ASTM F1978-18	(b)(4)				

Table 12-3. Implant Performance Testing Related to NKB Product Code

Link to Ref	Test and Compliance	Sample and Sample Size	Acceptance Criteria	Results	PASS/ FAIL	Equivalence Conclusion
Construct (ASTM F1717) Testing Bedrock Granite Test Protocol and Report (b)(4)	Construct Testing ASTM F1717	(b)(4)				

In summary, test results demonstrate that the subject device met the performance specifications for both OUR and NKB product codes (refer to **Table 12-2**, **Table 12-3**, and **Attachment 12B**). As such, the verification and validation testing confirmed that the subject device is substantially equivalent to the predicate devices, as applicable.

(b)(4)

12.2 Device-Specific Guidance Document

This performance testing section was prepared in accordance with the applicable parts of:

- Spinal System 510(k)s Guidance Document, dated May 2004
- Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements, dated February 2000

Table 12-5 lists specific guidances or standards followed for subject device testing.

Table 12-5: Device Specific Guidance Document Performance Testing

Test	Guidance Recommendation
Static and Dynamic Cantilever Bending per ASTM F2913	FDA Recognized test methods used for SI fusion devices
Static Torsion per ASTM F543	
Static Axial Pullout per ASTM F543	
Static and Dynamic Axial Compression per ASTM F1717	FDA Recognized test methods used for posterior pedicle screw systems. In accordance with Guidance Document:

Test	Guidance Recommendation
Static Axial Torsion per ASTM F1717	Spinal System 510(k)s Guidance Document, dated May 2004
Static Shear per ASTM F1044	FDA Recognized test methods for coatings which can be applicable to porous layers. In accordance with Guidance Document: Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements, dated February 2000
Shear Fatigue per ASTM F1160	
Static Tension per ASTM F1147	
Abrasion per ASTM F1978	

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ATTACHMENT 14B

510(k) Summary

In accordance with 21 CFR 807.92, a separate, stand-alone 510(k) Summary is provided herein.

510(k) SUMMARY

(b)(4)

(b)(4)

(b)(4)

Hi Sean,

SI-BONE agrees with FDA's proposed edits to the IFU for the iFuse Bedrock Granite Implant System. Please find attached the updated copies of the 510(k) summary and FDA Form 3881.

We also confirm that Labeling documents will be revised with the new indications for use. Thanks for your review and updates.

Have a good evening.

Thanks and regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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471 El Camino Real, Suite 101, Santa Clara, CA 95050

Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

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From: Miller, Sean <Sean.Miller@fda.hhs.gov>

Sent: Thursday, January 18, 2024 11:45 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com>

Cc: K233508@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

After some internal discussion, we are suggesting a few revisions for the proposed indications for use. I've attached a document that compares your original proposed indications and our revisions in red. A clean version is located below the comparison table.

The main points of the revisions are as follows:

(b)(4)

Please examine the proposed revisions, and feel free to ask any questions you may have or suggest further modifications.

Once we come to an agreement on the indications, please submit updated copies of FDA form 3881 and the 510(k) summary. Please also confirm that Labeling documents will be revised with the new indications for use.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Thursday, January 18, 2024 12:34 PM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hi Sean,

I am following up to see if you have any updates on K233508. Do you think we will be receiving the questions either today or tomorrow?

Thanks and have a good day!

Best regards,

Jai Prabakaran

Associate Director, Regulatory Affairs

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Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

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From: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Sent: Thursday, January 11, 2024 1:39:34 PM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Subject: RE: [EXTERNAL] RE: K233508 review will proceed via interactive review

Hi Jai,

I should have our feedback to you by next Wednesday at the latest. Sorry for the delay in response, reviews around the holidays can get a bit hectic.

Thank you,

Sean

From: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Sent: Monday, January 8, 2024 11:28 AM

To: Miller, Sean <Sean.Miller@fda.hhs.gov<mailto:Sean.Miller@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K233508 review will proceed via interactive review

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Hello Mr. Miller,

Happy New Year and thanks for the update. May I know when we will receive the interactive review questions for K233508?

If you need any additional information, please let me know.

Thanks and regards,

Jai Prabakaran, MBS (Regulatory & Clinical), RAC

Associate Director, Regulatory Affairs

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Jayasri.Prabakaran@SI-Bone.com<mailto:Jayasri.Prabakaran@SI-Bone.com>

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From: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Sent: Friday, December 29, 2023 7:15 AM

To: Jayasri (Jai) Prabakaran <Jayasri.Prabakaran@si-bone.com<mailto:Jayasri.Prabakaran@si-bone.com>>

Cc: Sean Miller [SEAN.MILLER] <sean.miller@fda.hhs.gov<mailto:sean.miller@fda.hhs.gov>>

Subject: K233508 review will proceed via interactive review

December 29, 2023

Substantive Review Notification - Proceed Interactively

FDA has completed a substantive review of your submission K233508 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.

*** This is a system-generated email notification ***

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