Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

RENOVIS

Abbreviated 510(k) Summary
as required by 21 CFR 807.92(a)
K131122

A) Submitted by: Renovis Surgical Technologies
1901 W. Lugonia Ave, Ste 340
Redlands, CA 92374
Phone: 909-557-2360
Fax: 909-307-8571

Official Contact: Anthony DeBenedictis
Vice President of Quality Assurance

Consultant: Sharyn Orton, Ph.D.
MEDIcept, Inc. 200
200 Homer Ave
Ashland, MA 01721

SEP 18 2013

Date Prepared: September 16, 2013

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System

Device Class: Class II – 888.3080

Regulation and Product code: 888.3080, OVD - Intervertebral body fusion device

Classification panel: Orthopedic

C) Predicates:
- K081177 Blackstone Orthofix Pillar
- K092211 K2M Chesapeake
- K123767 Lanx Lateral –SA System
- K102738 Lanx Fusion System
- K083815 Lanx Fusion System
- K073144 Lanx Intervertebral Body Fusion Device
- K082260 Calvary Spine Petra PLIF Cage System

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

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RENOVIS

D) Device Description:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is to be used with the bone screws and anterior cover plate assembly and requires no additional supplementary fixation systems. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The Renovis S128 ALIF System contains both fixed and variable angle screw options. The fixed angle screw option provides a tight fit with the cage. The variable angle screw option provides a slight clearance between the cage and the screw which allows for a small amount of variable screw angulations.

The Renovis S128 ALIF System cages are intended to be used with autogenous bone graft. The accompanying cover plate is designed to prevent screw back-out and must be used when the screws are implanted. NOTE: The cover plate assembly and screw are part of the implant construct.

The Renovis S128 ALIF System implants are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and coverplate assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum. The Renovis S128 ALIF System is used with trials and implant specific manual instruments, and includes other class I manual orthopedic instruments.

E) Indications For Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

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

F) Substantial Equivalence Comparison and Discussion

	Renovis S128 ALIF System	Blackstone (Orthofix) Pillar K081177	K2M Chesapeake K092211	Lanx Lateral SA System K123767 Fusions System K102738 Fusion System K083815 Intervertebral body Fusion Device K073144	Calvary Spine Petra PLIF Cage System K082260
Implant Material	PEEK Titanium	PEEK	PEEK	PEEK Titanium alloy	PEEK
Dimensions in mm A/P M/L H	 26, 28, 30 30, 34, 38 11 - 21	 28, 32 37, 40, 43 12.5 - 20	 24, 28, 30 30, 36, 40 11-19	 16, 18, 22, 26 25 to 60 6-16	 Crescent 13x 27 Straight 11 x 30 7-15
Lordosis	7°, 12°	7°, 12°	10^0, 15^0	0o, 80	80
Screw material	Titanium	Titanium	Titanium	Titanium when applicable	Requires supplemental fixation
Number of screws	4	4	3	Unk	
Screw Diameter (mm)	4.5, 5.0	5.0, 5.5	5.5	Unk	
Screw Length (mm)	20, 25, 30, 35	20, 25, 30, 35	20, 25, 30	Unk	
Cover plate	Titanium	Titanium	Titanium	Unk	
Marker material	Tantalum	Tantalum	Tantalum	Tantalum	Tantalum

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Conclusion

Based upon the same or similar intended use, design, function, technology, and materials, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

G) Performance Testing

The Renovis S128 ALIF System implants (worse case constructs) have successfully undergone the following testing:

1. Static Compression per ASTM F2077
2. Dynamic Compression per ASTM F2077
3. Static Shear-Compression per ASTM F2077
4. Dynamic Shear-Compression per ASTM F2077
5. Expulsion Testing w/screws per ASTM Draft Standard F04.25.02.02
6. Expulsion Testing w/o screws per ASTM Draft Standard F04.25.02.02
7. Subsidence testing per ASTM F2267

Sample coupons of the Titanium porous structure have successfully undergone the following testing:

1. Shear testing of metallic coatings per ASTM F1044
2. Tensile testing of metallic coatings per ASTM F1147
3. Abrasion per ASTM F1978
4. Porosity and microstructure per ASTM F1854

Conclusion

Performance data results support that the Renovis S128 ALIF System is substantially equivalent to the predicate devices and that there are no new issues of safety or effectiveness.

H) Compliance with FDA Guidance and Consensus Standards

The Renovis S128 ALIF System complies with the following:

FDA Guidance:

- Guidance Document Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", June 12, 2007.
- Guidance for Industry and FDA Staff: Spinal System 510(k)s", May 2004 for labeling including labels, Instructions for Use and Surgical Manual

21 CFR 888.3080 Intervertebral body fusion device:

- ASTM F 983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components

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- ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ASTM F2267-04 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM F2077-3 Test Methods for Intervertebral Body Fusion Devices

Other

- ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F-136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, and
- ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ASTM draft standard F.04.25.02.02 Static Expulsion
- ASTM F1044-05(2011)e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1147- 05(2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1978 – 12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- ASTM F1854 - Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM A564 - Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- ASTM F138 - Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

September 18, 2013

Renovis Surgical Technologies, LLC
% Sharyn Orton, Ph.D.
MEDIcept, Incoporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K131122
Trade/Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: August 16, 2013
Received: August 19, 2013

Dear Dr. Orton.

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

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

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

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

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

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

Sincerely yours,

Ronald P. Jean -S for

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

Enclosure

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

Indications for Use Form

510(k) Number (if known): K131122

Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use:

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Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(21 CFR 801, Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

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

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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

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K131122/A001

MEDICEPT
Medical Device Compliance Consulting

FDA CDRH DMC
MAY 03 2013
Received

May 1, 2013

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: K131122/A001 – Abbreviated 510(k) Premarket Notification for the Renovis S128 ALIF System

To Whom it May Concern:

Please accept this revised Cover Letter that contains corrections to the address of my client, Renovis Surgical Technologies.

The original cover letter incorrectly indicated the following address: 10415 Morado Circle, Building 1, Suite 220, Austin, TX 78759. The correct address is: 1901 W. Lugonia Ave, Suite 340, Redlands, CA 92374. All other references to the address within the application (FDA Form 3514 and the 510(k) Summary) are correct.

The eCopy is an exact duplicate of the paper copy and contains a copy of this cover letter.

If there are any questions regarding this submission, please contact me at 401-330-8264 or by email at sorton@medicept.com.

Sincerely yours,

Sharyn Orton

Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Inc.
for
Renovis Surgical Technologies

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

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MEDICEPT
Medical Device Compliance Consulting

May 1, 2013

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

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K131122/A2

MEDICEPT
Medical Device Compliance Consulting

FDA CDRH DMC
AUG 27 2013
Received

August 26, 2013

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

Re: K131122/S002 – Response to Additional Information Request – Additional Information for Deficiency 1 - Abbreviated 510(k) Renovis S128 ALIF System

Dear Ms. Kavlock:

Our response to the Additional Information request received by email on 6/19/2013 was submitted to the FDA on August 16, 2013. (b)(4) [redacted]

(b)(4) [redacted]

"Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff", December 31, 2012.

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

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August 26, 2013

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

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TABLE OF FILES

Document name	File number
Cover letter K131122 S002	001
K131122 S002 Deficiency 1 Additional Information	002

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(b)(4) Deficiencies

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Volume 8, Number 1

Journal of the Spinal Research Foundation

New Horizons in Spine Treatment

SPRING 2013

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

4WEB Spinal Truss System™

Timothy Gainey, Ph.D.

The Annual Meeting of the North American Spine Society has always provided the perfect backdrop for original ideas and novel products, and supported a forum for creative exchange. This past year's NASS meeting in Dallas, TX did not disappoint those looking for innovation. One product in particular that garnered a lot of attention was the 4WEB Spinal Truss System. The cage was conceived by Jessee Hunt and initially developed as a device that would provide structural support for interbody fusion. Its open configuration was designed to sustain strength without impeding or restricting the potential for bone to grow into and through the implant. It is believed that by doing so, this new device would enable greater bone formation and fusion without compromising initial healing or mechanical support (Figure 1). Modeled from a truss structure, the inherent design goal was to extend the strain to the margins of the construct and reduce the concentration of forces at the surface of the implant in contact with the bony endplates—, essentially dissipating load broadly across the entire surface (Figure 2).

It has been known for some time that distribution and dissipation of stress are the hallmarks of bone remodeling. In that light, this device represents a unique foray into applied design that integrates the strength inherent to truss geometry, the architecture of static distribution force, and the dynamics of bone remodeling as a fresh therapeutic approach to spine surgery. Recent advances in engineering technology (additive fabrication in particular) have aligned, and a new potential for complex and intricate designs and structures previously unavailable to medical manufacturing has emerged. The 4WEB Truss Implant Technology represents a first opportunity to view that technology in a clinical application. A final design was evaluated and optimized by Lisa Ferrara, Ph.D. (OrthoKinetic Technologies, LLC, Southport, NC) that would effectively minimize the material and maximize the distribution of strain—her guidance defining lateralization of force and reduction of subsidence risk as an integrated facet of the process. The 4WEB truss was fabricated from medical grade titanium alloy using Electron Beam Welding, conferring a rigid truss structure that was subsequently validated for strength, stress, and strain distribution.

The 4WEB Spinal Truss System was subjected to a number of rigorous tests including finite element analysis, subsidence and mechanical performance evaluation, as well as a 12-month large animal study. Even with the greatest confidence in product design, sometimes it is not possible to anticipate the serendip-

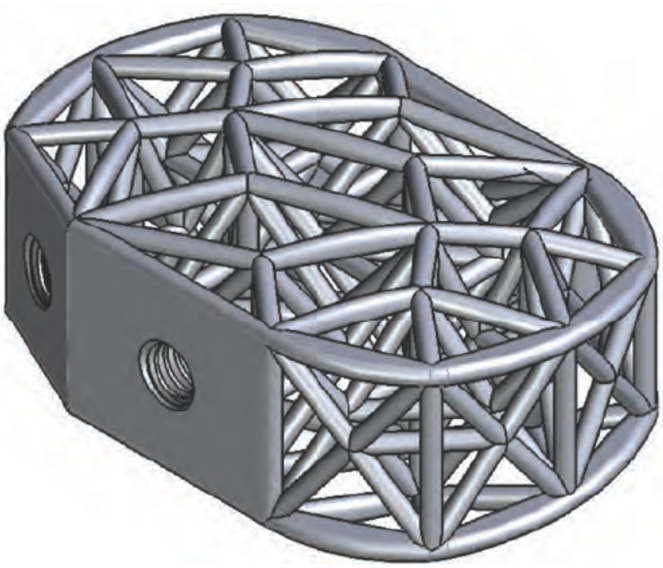

Figure 1. The 4WEB Spinal Truss System was designed to promote greater bone formation and fusion. *Image courtesy of 4WEB Inc.*

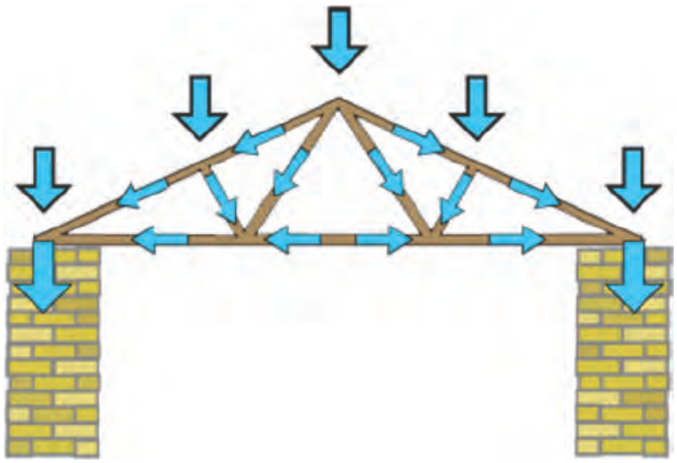

Figure 2. The 4WEB design is based upon truss geometry in order to disperse the load force across the structure's surface. *Image courtesy of 4WEB, Inc.*

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ity of biologic translation. Working with Peggy Lalor, Ph.D. (Histion, Inc., Everett, WA), a respected authority of bone pathology, Jessee was on pins and needles waiting for the histology results. Her remark of never having seen such profuse filling of an interbody spine fusion device filled with autograft at 3-months increased the excitement surrounding this technology. Several additional independent reviews and positive clinical reception from all physicians who have had the chance to interpret the histology, and an expedited review and clearance by FDA of the devices for clinical use as an ALIF for lumbar spine fusion, and more recently as a cervical fusion device validate the animal study results.

Assessments of the bone histology from the preclinical model offered insight into bone remodeling that under-anticipated the implications of the design. In an effort to lessen stress shielding, the 4WEB Spinal Truss System accentuated load sharing while hastening structural bone constructs that interfaced and accepted the truss load. Unprecedented amounts of bone were deposited throughout the cage that resulted in an integrated fusion mass throughout the cage.

The 4WEB Spinal Truss System—Load Transfer Design

The open web design increases volume for bone deposition, and at the same time, provides tensile struts that facilitate apposition. These effects were collaterally efficient, assuring biomechanical support analogous to rebar in cement and stimulating an osteogenic response via a load transfer mechanism. Wolf's Law describes the nature in which bone remodels, stating that bone in a healthy person or animal will adapt to the loads it is placed under to reduce strain. If loading on a particular bone increases, the bone will remodel over time to resist strain associated with loading and translate the force in tension.

Recent advances in applied bone biomechanics define optimal structural cues that encourage or escort bone remodeling. Insight emerging from this field addresses the eventuality of material evolution and the appearance of structural synergy with load bearing, strain energy density, and resultant bone formation. The innovation of the 4WEB geometric design incorporates unique engineering concepts that integrate truss resolution from global loading potentials resulting in augmented bone formation with unique reciprocity and reliance on trajectory driven loading (Figure 3). Impressive about bone formation around the construct is that bone that formed both inside and outside the 4WEB Spinal Truss System is matched (Figures 4a and 4b). The bone image inside the cage has been rendered at higher magnification to demonstrate the lamellar bone structure on both sides of the truss.

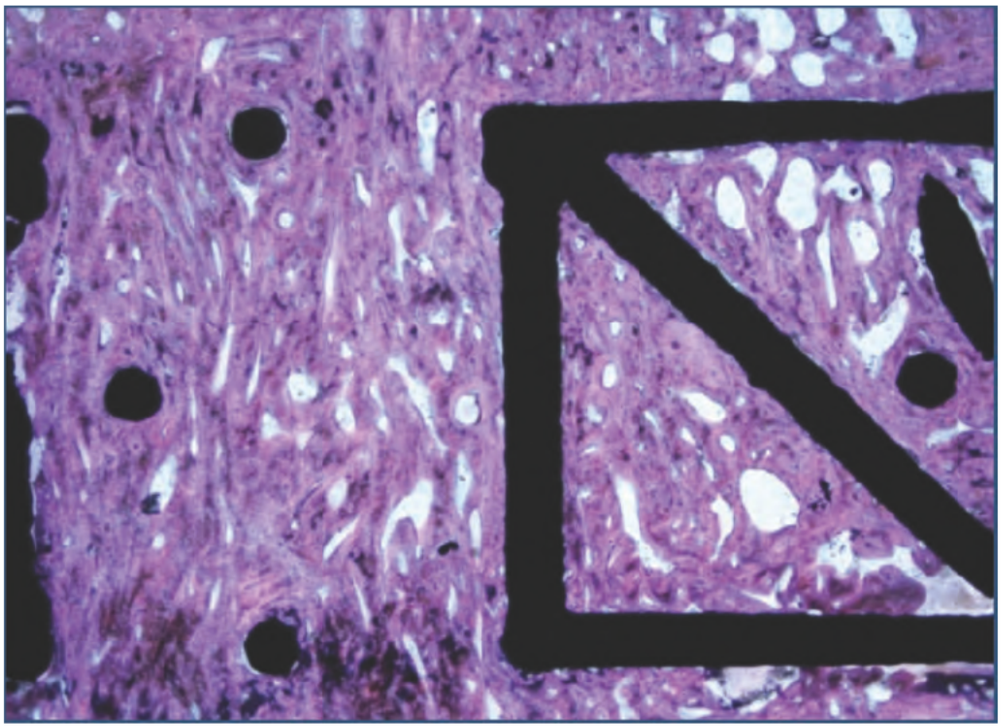

Figure 3. Bone formation utilizing the 4WEB Spinal Truss System. *Image courtesy of 4WEB, Inc.*

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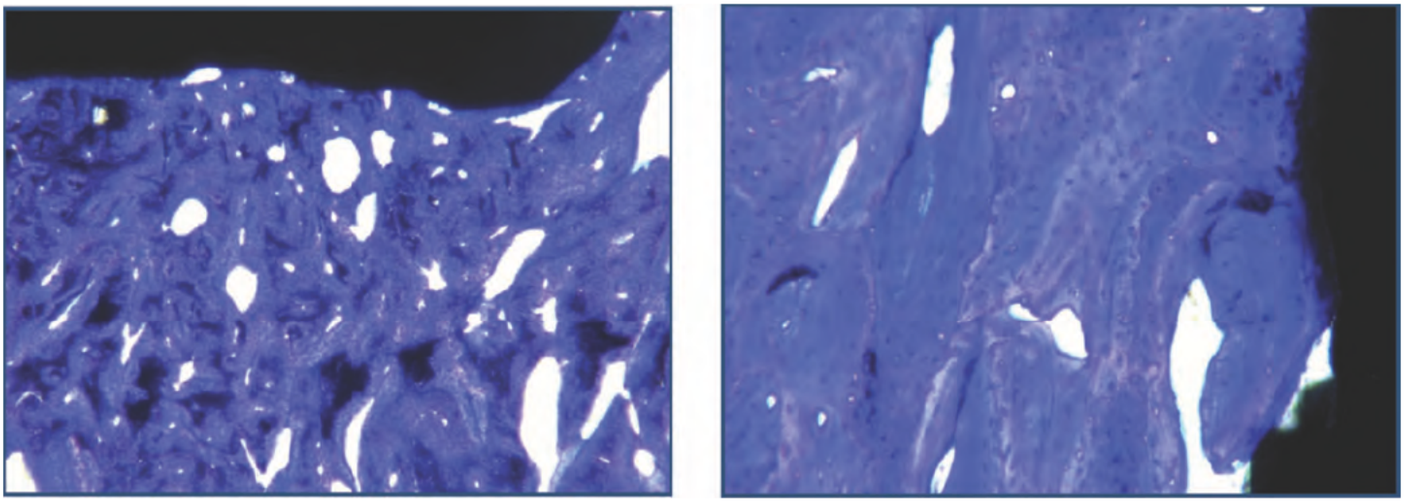

Figure 4. Left: bone formation outside of the 4WEB cage. Right: bone formation inside the 4WEB cage. *Images courtesy of 4WEB, Inc.*

The 4WEB Spinal Truss System—Surface Topology

The additive fabrication process used to manufacture the intricate 4WEB design results in a fully fused solid that has a micro texture surface topology/energy that has been shown to guide mesenchymal stem cells toward an osteogenic lineage. Presented at the AAOS, and later published in *The Spine Journal*, an evaluation of acid-etched titanium alloy surfaces was reported to guide stem cell osteogenic differentiation.[1] While the concept of surface topology triggering cell recognition and tissue differentiation is not a new concept, the 4WEB design maximizes this mechanical asset by providing the microstructure to all of the struts that run throughout the bone implant construct rather than restricting the surface topology to select contact surfaces seen in predicate devices.

Summary

The 4WEB Spinal Truss System utilizes the geometric distribution provided in a truss design to redistribute axial loading vectors and exploit the generation of shear forces that accentuate bone formation. This bone formation is highly organized, stabile, and hastens the deposition of structural lamellar bone in a very short time. Histopatholological assessment did not reveal any evidence of hypertrophic cartilage formation, suggest instability, or provide any evidence of inflammatory changes in the marrow that might resonate with chronic reactive bone.

Finite element analysis shored up a basis for stress distribution that would minimize the likelihood of subsidence while accentuating the open structure that would allow bone to pass throughout the construct and integrate with the two adjacent cranial and caudal vertebral bodies. Topologic surface features of titanium struts mirrored roughness assessments that have been shown to actively promote osteoblast phenotype and reduce surface proliferation. The added enhancement of the additive fabrication technology contributed and correlated with the impressive quality and substantial quantity of bone that was seen within the devices tested in the large animal model.

Although the 4WEB Spinal Truss System has only recently received FDA clearance for ALIF and ACDF procedures, available clinical data suggests that reduced pain, accelerated return to function, and demonstrated bone production are hallmarks of the success of the device. The robust response demonstrated radiographically at 4 months provides confidence that fusion is accelerated and that the open structure of the system does not hamper clinical evaluation (Figure 5). Given the accelerated forma-

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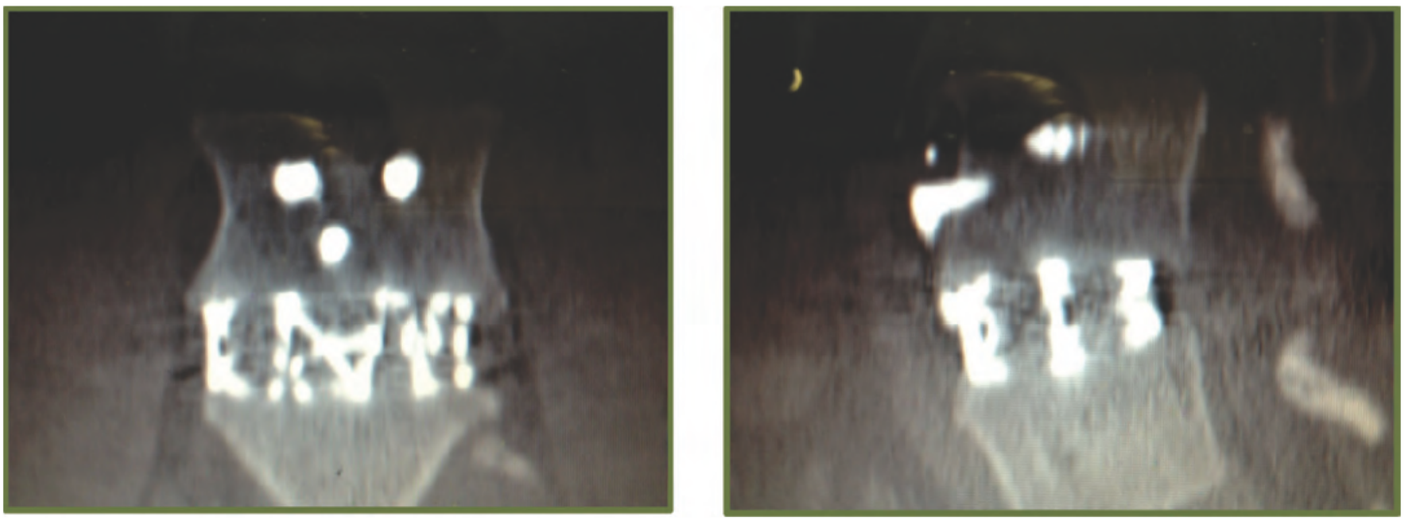

Figure 5. Radiographic evidence of fusion at 4 months after the cage was implanted. *Images courtesy of 4WEB, Inc.*

tion of bone and reduction of pain attendant to use of the 4Web geometry, perhaps the next consideration is then furthered by optimization of intent to achieve better clinical outcome, lessened patient morbidity, and demonstrated improvement in quality of life. Offering relief of pain, enhanced bone formation, and return to function, the 4WEB Spinal Truss System represents a tool affording a unique strategy for securing a stable fusion in treating degenerative disc disease.

REFERENCE

1. Olivares-Navarrete R, Gittens RA, Schneider JM, Hyzy SL, Haithcock DA, Ullrich PF, Schwartz Z, and Boyan BD. Osteoblasts exhibit a more differentiated phenotype and increased bone morphogenetic protein production on titanium alloy substrates than on poly-ether-ether-ketone. *The Spine Journal* 2012; 12:265–272 .

Timothy Gainey, Ph.D.

Tim Gainey is Director of Orthopaedic Research and Technology Development at the Atlanta Medical Center. He is also the recent President of co.don Tissue Engineering, a subsidiary of co.don AG. He has been published extensively in peer review journals and a lecturer at a variety of scientific meetings both domestically and overseas. Tim holds a B.S./B.A. degree at the University of Illinois and a Ph.D. degree at the University of South Florida. He is a member of eleven professional societies including the Orthopaedic Research Society and the American Association for the Advancement of the Sciences. He has also been honored by various professional and business organizations, most recently as the 2000 winner of the Outstanding Research Award, Sofamor-Danek Award, Australian Spine Society. Further, Tim is an Editorial Reviewer for industry publications including BioDrugs, Journal of Pediatric Orthopaedics, Tissue Engineering, Journal of Shoulder and Elbow Surgery.

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

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K08 6811 page 6 of 2

510(k) Summary according to 807.92(c)

JAN 18 2011

Date prepared: January 17, 2011

Contact: Jessee Hunt, President
4-Web Spine, Inc.
6629 Whispering Woods Ct.
Plano, TX 75024
972-841-6126

Trade Name: ALIF Spinal Truss System ® Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080 Orthosis, intervertebral fusion
Product Codes: MAX
Panel Code: 87

Indications for Use:
The ALIF Spinal Truss System (STS) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Device Description:
The ALIF STS Interbody Fusion Device is a titanium implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.

The device is available in three basic "footprint" sizes, small, medium and large. These sizes are available in zero degree lordosis and 8 degree lordosis and each of these in 8 heights ranging from 10mm to 17mm in 1mm increments.

Predicate Device(s):
The ALIF STS® Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. The predicate devices include the BAK Interbody Fusion Device (Spine-Tech, P950002), Infix System from Spinal Concepts (K031672) and the Brantigan Lumbar I/F Cage (AcroMed, P960025). (Add Titan Spine?)

Performance Testing:
Preclinical testing performed on the 4-Web STS® Interbody Fusion Device included static compression, static compression shear, static torsion, dynamic axial compression, and dynamic

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compressive shear mechanical testing per ASTM F2077. Other mechanical tests included subsidence per ASTM F2267-04 and expulsion testing per an industry accepted methodology. Finite Element Analysis to assess mechanical stiffness, quantify stresses and intra-cage pressure and to quantify porosity was also completed. Finally, an animal study in sheep which demonstrated fusion was performed. The outcome of pre-clinical testing performed indicates that the ALIF STS® Interbody Fusion Device is substantially equivalent to the predicate devices..

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

4-Web Spine, Inc.
% Richard Jansen, Pharm.D.
Silver Pine Consulting
13540 Guild Avenue
Apple Valley, Minnesota 55124

JAN 18 2011

Re: K083894
Trade/Device Name: ALIF Spinal Truss System® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 22, 2010
Received: December 27, 2010

Dear Dr. Jansen:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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

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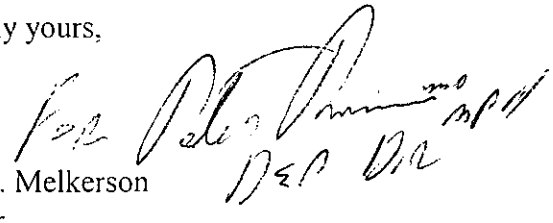
or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,



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

Enclosure

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016
K083894

Statement of Indications for Use

510(k) Number (if known): K083894

Indications for Use:

The ALIF Spinal Truss Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

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

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

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

510(k) Number K083894

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

Records processed under FOIA Request # 2015-3696, Released by CDRH on 03-15-2016

4WEB

DEC 1 4 2011

510(k) Summary according to 807.92(c)

Date prepared: January 17, 2011
Contact: Jessee Hunt, President
4-Web Spine, Inc.
6629 Whispering Woods Ct.
Plano, TX 75024
972-841-6126

Trade Name: ALIF Spinal Truss System ® Interbody Fusion Device
Product Class: Class II
Classification: 21 CFR §888.3080 Orthosis, intervertebral fusion
Product Codes: MAX
Panel Code: 87

Indications for Use:
The ALIF Spinal Truss Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Device Description:
The ALIF STS Interbody Fusion Device is a titanium implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.

The device is available in three basic "footprint" sizes, small, medium and large. These sizes are available in 0, 6, 8 and 12 degree lordosis and each of these in 9 heights ranging from 8mm to 17mm in 1mm increments.

Predicate Device(s):
The ALIF STS® Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. The predicate devices include the 4-Web

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

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Spine STS (K083894), the DePuy/AcroMed Brantigan Cage (P960025) and the Advanced Medical Technologies Distractable Wave Cage (K083626).

Performance Testing:
Preclinical testing performed on the 4-Web STS® Interbody Fusion Device included static compression, static compression shear, static torsion, dynamic axial compression, and dynamic compressive shear mechanical testing per ASTM F2077. Other mechanical tests included subsidence per ASTM F2267-04 and expulsion testing per an industry accepted methodology.

Design Changes to (K083894):
Design changes include reduced struts diameter, removal of struts, rounding the top and bottom rim, adding domed contact surfaces, rounding the posterior edge, adding thread ports, increasing the number of lordotic angles and heights available as well as adding one additional cross strut under the posterior rims. The modified design underwent the same performance testing as to the previously approved device. The results indicate equal to or better than performance to the original design or other previously approved devices.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

DEC 14 2011

4-Web Spine, Inc.
% Silver Pine Consulting, Ltd.
Rich Jansen, Pharm.D.
13450 Guild Avenue
Apple Valley, Minnesota 55124

Re: K112316
Trade/Device Name: ALIF Spinal Truss System® Interbody Fusion
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class:. Class II
Product Code: MAX
Dated: December 08, 2011
Received: December 09, 2011

Dear Dr. Jansen:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

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

Enclosure

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

Statement of Indications for Use

510(k) Number (if known): K112316

Indications for Use:

The ALIF Spinal Truss Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft bone. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K112316

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

K123747 Page 1 of 2

OCT 18 2012

510(k) Summary according to 807.92(c)

Date prepared:	January 17, 2011
Contact:	Jessee Hunt, President 4-Web, Inc. 6170 Research Road, Suite #219 Frisco, TX 75033 972-841-6126
Trade Name:	Cervical Spinal Truss System ® Interbody Fusion Device
Product Class:	Class II
Classification:	21 CFR §888.3080 Orthosis, intervertebral fusion
Product Codes:	ODP
Panel Code:	87

Indications for Use:
The 4-Web Cervical Spinal Truss System (STS) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. 4-Web Cervical STS implants are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device should be used with supplemental fixation.

Device Description:
The Cervical STS Interbody Fusion Device is a titanium implant that is designed to provide mechanical support to the lumbar spine while biologic fusion takes place. The device is an "open architecture" design consisting of trusses mathematically designed to provide maximum support with the greatest amount of open space throughout the implant for bone growth and fusion. The implant is made from Ti6Al4V alloy.

The device is available in two basic "footprint" sizes, 17mm x 14mm and 14mm x 11mm. These sizes are available in zero and 7 degree lordosis and each of these in 8 heights ranging from 5mm to 12mm in 1mm increments.

Predicate Device(s):
The Cervical STS® Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. The predicate devices include the BAK/C (P980048), Phantom Plus Cage (K082801), Endoskeleton TC (K100889) and for manufacturing and materials purposes, the 4-Web ALIF STS (K083894, K112316).

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

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Performance Testing:
Preclinical testing performed on the 4-Web Cervical STS® Interbody Fusion Device included static axial compression, static compression shear, static torsion, dynamic axial compression, dynamic compressive shear and dynamic torsion mechanical testing per ASTM F2077. Other mechanical tests included subsidence per ASTM F2267-04 and expulsion testing per an industry accepted methodology.

Conclusion:
4-Web, Inc concludes that the Cervical STS device is the same intended use as the predicate devices. The indications for use are the same and the materials used are also the same as the predicate devices. There are no significant differences in technological characteristics compared to the predicates, and the minor differences that do exist do not raise any new types of safety or efficacy issues. Furthermore, bench testing demonstrates that these differences do not adversely impact device performance. 4-Web concludes that the Cervical STS device is substantially equivalent to the predicate devices.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

4-Web, Incorporated
% Silver Pine Consulting, Limited
Mr. Richard Jansen, Pharm. D.
Consultant
13540 Guild Avenue
Apple Valley, Minnesota 55124

OCT 18 2012

Re: K121741
Trade/Device Name: Cervical Spinal Truss System® Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 01, 2012
Received: October 02, 2012

Dear Mr. Jansen:

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

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

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

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

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

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

Sincerely yours,

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

Enclosure

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

Statement of Indications for Use

510(k) Number (if known): K121741

Indications for Use:

The 4-Web Cervical Spinal Truss System (STS) is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. 4-Web Cervical STS implants are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device should be used with supplemental fixation.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K121741

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

September 18, 2013

Renovis Surgical Technologies, LLC
% Sharyn Orton, Ph.D.
MEDIcept, Incoporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K131122
Trade/Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: August 16, 2013
Received: August 19, 2013

Dear Dr. Orton.

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

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

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

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

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

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

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

Sincerely yours,

Ronald P. Jean -S for

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

Enclosure

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

Indications for Use Form

510(k) Number (if known): K131122

Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

Prescription Use ___X___ (21 CFR 801, Subpart D) AND/OR Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

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

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

K131122

MEDICEPT
Medical Device Compliance Consulting

FDA CDRH DMC
APR 22 2013
Received

April 18, 2013

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: Abbreviated 510(k) Premarket Notification for the Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

To Whom it May Concern:

This Abbreviated 510(k) Premarket Notification application for the Renovis S128 Anterior Lumbar Interbody Fusion (IBF) System ("Renovis S128 ALIF System") is being submitted by MEDIcept, Inc. on behalf of our client Renovis Surgical Technologies, 10415 Morado Circle, Building 1, Suite 220, Austin, TX 78759, registration number 3007932279. The contact person for this application is Sharyn Orton, Ph.D., Senior Consultant, MEDIcept, Inc.; phone number 401-330-8264; email sorton@medicept.com.

The eCopy is an exact duplicate of the paper copy with the following exception:

- The numerous engineering drawings for the Implants (42) and Instruments (38) are located in MISC FILES and are not printed in the hard copy of the application.

The folder MISC FILES also contains Word copies of the following:

- S128 Anterior Lumbar Interbody Fusion (IBF) System Instructions of Use
- S128 ALIF System Surgical Technique
- 4001-001 Surgical Instruments Instructions for Use

The files have been paginated per the FDA "Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff", December 31, 2012.

Administrative Information and Basis of Submission

The Renovis S128 ALIF System is new Class II device and qualifies for the designation "510(k) Notification" per 21 CFR 807.90(e). This application is submitted as an Abbreviated 510(k) Premarket Notification, in compliance with "Guidance Document Guidance for Industry and

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

31

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", June 12, 2007.

- Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar
- Common Name: Intervertebral body fusion device
- Proprietary Name: Renovis 128 Anterior Lumbar Interbody Fusion (ALIF) System
- Device Class II – 21 CFR 888.3080, product code MAX

There are no previous FDA document numbers associated with formal correspondence with FDA, e.g., IDE, pre-IDE, pre-Sub 510(k), PMA, request for designation (RFD), NSE letter, or AI letter with withdrawal for this device.

Brief Description

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System consists of implants (cages) that are to be used with autogenous bone graft, as well as bone screws and an anterior cover plate assembly. The cover plate assembly and screw are part of the implant construct. The Renovis S128 ALIF System requires no additional supplementary fixation system.

The Renovis S128 ALIF System implants are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and cover plate assembly are both manufactured from Titanium alloy. The PEEK Implants include markers manufactured from Tantalum. The Renovis S128 ALIF System is used with trials and implant specific manual instruments, and includes other class I manual orthopedic instruments.

Design and Use of the Device

- The Renovis S128 ALIF System is for prescription use only.
- All Renovis S128 ALIF System components (implants, cover plates and screws, trials and instruments) are provided non-sterile and must be sterilized before use.
- No Renovis S128 ALIF System component contains tissue or other biologic material.
- Renovis S128 ALIF implants, cover plates and screws are single use only. Trials and instruments are reusable.
- There is no software associated with this device.
- There is no clinical data included in this application.

Indications for Use

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

(DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

This Premarket Notification includes trade secret and commercial information that is privileged or confidential and, in accordance with 21 CFR 20.61, is not available for public disclosure. Therefore, we request continued confidentiality (21 CFR 807.95).

In accordance with the Safe Medical Device Act of 1990, a 510(k) Summary is included in this notification. The 510(k) Summary, Indications for Use Statement, and Truthful and Accurate Statement are included along with other required contents of an Abbreviated 510(k) Premarket Notification.

This device will not be offered for sale until we first receive FDA clearance of our device as defined by the regulation. If there are any questions regarding this submission, please contact me at 401-330-8264 or by email at sorton@medicept.com.

Sincerely yours,

Sharyn Orton

Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Inc.
for
Renovis Surgical Technologies

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016
Form Approved: OMB No 0910-511 Expiration Date: February 28, 2013 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted] Write the Payment Identification number on your check.

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

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
RENOVIS SURGICAL TECHNOLOGIES INC 1901 W Lugonia Ave # 340 Redlands CA 923749703 US	Jathan Merkel 2.1 E-MAIL ADDRESS jmerkel@renovis-surgical.com 2.2 TELEPHONE NUMBER (include Area code) 909-557-2360 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****2814	

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/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

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

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

NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: (b)(4) [redacted]

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

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

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

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

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

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

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

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

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

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

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

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

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

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted]

11-Apr-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

April 18, 2013

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: Abbreviated 510(k) Premarket Notification for the Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", June 12, 2007.

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

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Sincerely yours,

Sharyn Orton

Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Inc.
for
Renovis Surgical Technologies

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

Screening Checklist for Special 510(k) Premarket Notification Submissions

Title	Related Information	Present	N/A
MDUFMA Cover Sheet		x	
FDA Form 3514	CDRH Premarket Review Submission Cover Sheet	x	
FDA Form 3674	Certification of Compliance under 42 U.S.C 282(j)(5)(B) with Requirements of ClinicalTrials.gov Data Bank (42. U.S.C.282(j))	x	
FDA Form 3654	Guidance for Industry and FDA Staff: Recognition and Use of Consensus Standards, September 17, 2007:	x	
510(k) Cover Letter	Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, August 12, 2005	x	
Indications for Use Statement		x	
510(k) Summary		x	
Truth and Accuracy Statement		x	
Class III Summary and Certification			x
Financial Certification or Disclosure Statement			x
Conformity with Standards; Guidance		x	
Declaration of Conformity with Guidance or Special Controls		x	
Executive Summary		x	
Device Description		x	
Substantial Equivalence Discussion		x	
Labels and Proposed Labeling		x	
Cleaning/Sterilization/Shelf Life		x	
Biocompatibility		x	
Design Requirements	Per Special Control guidance document UCM071408	x	
Risk analysis		x	
Software	Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s, August 12, 2005: GuidanceDocuments/ucm084365.htm		x
Electromagnetic Compatibility/Electrical Safety			x
Performance Testing – Bench		x	
Performance Testing – Animal			x
Performance Testing – Clinical			x
Kit Certification	Device Advice: Kit Certifications for 510(k)s		x

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04/18/2013	(b)(4) [redacted]	

SECTION A — TYPE OF SUBMISSION

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

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

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

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Renovis Surgical Technologies	Establishment Registration Number *(if known)*: 3007932279		
Division Name *(if applicable)*:	Phone Number *(including area code)*: 909-557-2360		
Street Address: 1901 W. Legonia Ave, Ste 340	FAX Number *(including area code)*: 909-307-8571		
City: Redlands	State / Province: CA	ZIP/Postal Code: 92374	Country: USA
Contact Name: Anthony DeBenedictus			
Contact Title: VP of Quality Assurance	Contact E-mail Address: adebenedictus@renovis-surgical.com		

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

Company / Institution Name: MEDIcept, Inc.			
Division Name *(if applicable)*:	Phone Number *(including area code)*: 401-330-8264		
Street Address: 200 Homer Ave	FAX Number *(including area code)*: 508-231-8861		
City: Ashland	State / Province: MA	ZIP Code: 01721	Country: USA
Contact Name: Sharyn Orton, Ph.D.			
Contact Title: Senior Consultant	Contact E-mail Address: sorton@medicept.com		

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

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

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

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

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

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

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

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

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

- [ ] Response to FDA correspondence:

- [ ] Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- [ ] Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- [ ] Other Reason *(specify)*:

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	K081177	2	K092211	3	K123767	4	K102738
5	K083815	6	K073144	7	K082260	8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K081177	1	Pillar	1	Blackstone (Orthofix)
2	K092211	2	Chesapeake	2	K2M
3	K123767	3	SA System	3	Lanx
4	K102738, K083815	4	Fusion System	4	Lanx
5	K073144	5	Intervertebral Body Fusion Device	5	Lanx
6	K082260	6	Petra PLIF Cage System	6	Calvary Spine

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Intervertebral Body Fusion Device

	Trade or Proprietary or Model Name for This Device		Model Number
1	S128 Anterior Lumbar Interbody Fusion (ALIF) System	1	numerous
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code: MAX

C.F.R. Section *(if applicable)*: 888.3080

Classification Panel: Orthopedic

Device Class

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician cho

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

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Renovis Surgical Technologies		Establishment Registration Number: 30007932279
Division Name *(if applicable)*		Phone Number *(including area code)*: 909-557-2360
Street Address: 1901 W. Lugonia Ave, Ste 340		FAX Number *(including area code)*: 909-307-8571
City: Redlands	State / Province: CA	ZIP Code: 92374 / Country: USA
Contact Name: Anthony DeBenedictus	Contact Title: VP of Quality Assurance	Contact E-mail Address: adebendictus@renovis-surgical.com

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

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

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F136-11	ASTM	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications		10/4/2010
2		ASTM	draft standard F.04.25.02.02 Static Expulsion		
3	F1044-05(2011)e1	ASTM	Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings		8/20/2012
4	F1147-05(2011)	ASTM	Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings		8/20/2012
5	F1978-12	ASTM	Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser		1/15/2013
6	F1854-09	ASTM	Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants		10/4/2010
7	A564	ASTM	Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes		

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

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

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

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

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

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

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F138-08	ASTM	Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants		9/8/2009
2	983-06(reapproved 2011)	ASTM	Standard Practice for Permanent Marking of Orthopaedic Implant Components		10/4/2012
3	F565-04 (reapproved 2009) e1	ASTM	Standard Practice for Care and Handling of Orthopedic Implants and Instruments		10/4/2012
4	F2267-04	ASTM	Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression		8/20/2012
5	F2026-10	ASTM	Standard Specification for PEEK Polymers for Surgical Implant Applications		3/16/2012
6	F-136-11	ASTM	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications,		8/20/2012
7					

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

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

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

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Records processed under FOIA Request # 2015-8696, Released by CDRH on 03-15-2016

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Renovis Surgical Technologies

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
04/17/2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
1901 W. Lugonia Ave, Ste 340
Redlands, CA 92374

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 909-557-2360
(Fax)

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)
S128 Anterior Lumbar Interbody Fusion (IBF) System, Class II, multiple model numbers for system components

APPLICATION / SUBMISSION INFORMATION

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

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

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

CERTIFICATION STATEMENT / INFORMATION

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

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

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

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

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

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Sharyn Orton
Sign

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Sharyn Orton, Ph.D.
(Title) Senior Consultant

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
Medicept, Inc.
200 Homer Ave
Ashland, MA, 01721

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 401-330-8264
(Fax) 508-231-8861

15. DATE OF CERTIFICATION
4/17/2013

Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 443-6740 EF

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

4-1

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

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-183		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
• ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION
This is not a testing standard; this is a material specification standard and conformity is claimed by the material manufacturer

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM draft standard F.04.25.02.02 Static Expulsion

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

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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

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

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F1044-05(2011)e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-112		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
• ASTM F1044-05(2011)e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
This is a material test method standard and conformity is claimed by the material manufacturer

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

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

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F1147- 05(2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-113		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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

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STANDARD TITLE
•• ASTM F1147- 05(2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
This is a material test method standard and conformity is claimed by the material manufacturer

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F1978 – 12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Ta

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-330		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

• ASTM F1978 – 12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Ta

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

This is a material test method standard and conformity is claimed by the material manufacturer

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F1854 - Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-192		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
• • ASTM F1854 - Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
This is a material test method standard and conformity is claimed by the material manufacturer

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM A564 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes

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

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM A564 Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
This is a material test method standard and conformity is claimed by the material manufacturer

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F138-08 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#8-169	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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STANDARD TITLE
ASTM F138-08 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
This is a material test method standard and conformity is claimed by the material manufacturer

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F 983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#11-197	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
• ASTM F 983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
This is not a testing standard; it is a marking standard

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

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

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Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#11-199	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
• ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
This is not a testing standard; it is a labeling standard

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

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

Paperwork Reduction Act Statement

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

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F2267-04 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#11-185	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F2077-3 Test Methods for Intervertebral Body Fusion Devices

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

Title of guidance: Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

• ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-203		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
• ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION
This is not a testing standard; this is a material specification standard and conformity is claimed by the material manufacturer

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

• ASTM F-136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgic

CONFORMANCE WITH STANDARD SECTIONS*

(b)(4)

[redacted]

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

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

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

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

•• ASTM F-136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgic

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 8-219		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☐	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☐
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☐
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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

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

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Indications for Use Form

510(k) Number (if known):

Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

Indications for Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

Prescription Use____X_____ AND/OR Over-the-Counter Use _____
(21 CFR 801, Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

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

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

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RENOVIS

Abbreviated 510(k) Summary
as required by 21 CFR 807.92(a)

A) Submitted by: Renovis Surgical Technologies
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B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System

Device Class: Class II – 888.3080

Regulation and Product code: 888.3080, MAX - Intervertebral body fusion device

Classification panel: Orthopedic

C) Predicates:
- K081177 Blackstone Orthofix Pillar
- K092211 K2M Chesapeake
- K123767 Lanx Lateral –SA System
- K102738 Lanx Fusion System
- K083815 Lanx Fusion System
- K073144 Lanx Intervertebral Body Fusion Device
- K082260 Calvary Spine Petra PLIF Cage System

D) Device Description:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is to be used with the bone screws and anterior cover plate assembly and requires no additional supplementary fixation

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systems. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The Renovis S128 ALIF System contains both fixed and variable angle screw options. The fixed angle screw option provides a tight fit with the cage. The variable angle screw option provides a slight clearance between the cage and the screw which allows for a small amount of variable screw angulations.

The Renovis S128 ALIF System cages are intended to be used with autogenous bone graft. The accompanying cover plate is designed to prevent screw back-out and must be used when the screws are implanted. NOTE: The cover plate assembly and screw are part of the implant construct.

The Renovis S128 ALIF System implants are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and coverplate assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum. The Renovis S128 ALIF System is used with trials and implant specific manual instruments, and includes other class I manual orthopedic instruments.

E) Indications For Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

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F) Substantial Equivalence Comparison and Discussion

	Renovis S128 ALIF System	Blackstone (Orthofix) Pillar K081177	K2M Chesapeake K092211	Lanx Lateral SA System K123767 Fusions System K102738 Fusion System K083815 Intervertebral body Fusion Device K073144	Calvary Spine Petra PLIF Cage System K082260
Product code	MAX	MAX	MAX	MAX	MAX
Implant Material	PEEK Titanium	PEEK	PEEK	PEEK Titanium alloy	PEEK
Dimensions in mm A/P M/L H	 26, 28, 30 30, 34, 38 11 - 21	 28, 32 37, 40, 43 12.5 - 20	 24, 28, 30 30, 36, 40 11-19	 16, 18, 22, 26 25 to 60 6-16	 Crescent 13x 27 Straight 11 x 30 7-15
Lordosis	7°, 12°	7°, 12°	10^0, 15^0	0^0, 8^0	8^0
Screw material	Titanium	Titanium	Titanium	Titanium when applicable	Requires supplemental fixation
Number of screws	4	4	3	Unk	
Screw Diameter (mm)	4.5, 5.0	5.0, 5.5	5.5	Unk	
Screw Length (mm)	20, 25, 30, 35	20, 25, 30, 35	20, 25, 30	Unk	
Cover plate	Titanium	Titanium	Titanium	Unk	
Marker material	Tantalum	Tantalum	Tantalum	Tantalum	Tantalum

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Conclusion

Based upon the same or similar intended use, design, function, technology, and materials, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

G) Performance Testing

The Renovis S1128 ALIF System implants (worse case constructs) have successfully undergone the following testing:

1. Static Compression per ASTM F2077
2. Dynamic Compression per ASTM F2077
3. Static Shear-Compression per ASTM F2077
4. Dynamic Shear-Compression per ASTM F2077
5. Expulsion Testing w/screws per ASTM Draft Standard F04.25.02.02
6. Expulsion Testing w/o screws per ASTM Draft Standard F04.25.02.02
7. Subsidence testing per ASTM F2267

Sample coupons of the Titanium porous structure have successfully undergone the following testing:

1. Shear testing of metallic coatings per ASTM F1044
2. Tensile testing of metallic coatings per ASTM F1147
3. Abrasion per ASTM F1978
4. Porosity and microstructure per ASTM F1854

Conclusion

Performance data results support that the Renovis S128 ALIF System is substantially equivalent to the predicate devices and that there are no new issues of safety or effectiveness.

H) Compliance with FDA Guidance and Consensus Standards

The Renovis S128 ALIF System complies with the following:

FDA Guidance:

- Guidance Document Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", June 12, 2007.
- Guidance for Industry and FDA Staff: Spinal System 510(k)s", May 2004 for labeling including labels, Instructions for Use and Surgical Manual

21 CFR 888.3080 Intervertebral body fusion device:

- ASTM F 983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components

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- ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ASTM F2267-04 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM F2077-3 Test Methods for Intervertebral Body Fusion Devices

Other

- ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F-136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, and
- ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ASTM draft standard F.04.25.02.02 Static Expulsion
- ASTM F1044-05(2011)e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1147- 05(2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1978 – 12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- ASTM F1854 - Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM A564 - Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- ASTM F138 - Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants

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PREMARKET NOTIFICATION
TRUTH & ACCURACY STATEMENT
(AS REQUIRED BY 21 CFR 807.87(j))

I certify that, in my capacity as Vice President of Quality Assurance of Renovis Surgical Technologies, 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.

Anthony DeBenedictis

Signature

Anthony DeBenedictis

Print Name

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Date

*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).

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Conformity to Consensus Standards

Standards

The Renovis ALIF System complies with the following standards as appropriate for the device. No alternative testing was performed; there were no adaptations and no deviations. There were no differences between the tested device and the device to be marketed.

Regulated under 21 CFR 888.3080 Intervertebral body fusion device:

- ASTM F 983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components
- ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ASTM F2267-04 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM F2077-3 Test Methods for Intervertebral Body Fusion Devices

Other

- ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F-136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, and
- ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
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- ASTM F1044-05(2011)e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
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- ASTM A564 - Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- ASTM F138 - Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants

ASTM F2077-3 versus ASTM 2077-11 comparison

Testing of the Renovis S128 ALIF System implants was initiated per ASTM F2077-3 prior to the ASTM F2077-11 publication date of 8/12/2012 (located on the FDA website). The difference between the two standards include the following for -11:

- New - 1.4 These tests are designed to characterize the structural integrity of the device and are not intended to test the bone-implant interface.

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- New 1.8 - The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard, with the exception of angular measurements, which may be reported in terms of either degrees or radians.
  Compared to previous 1.7 which stated The values stated in SI units are to be regarded as the standard with the exception of angular measurements, which may be reported in terms of either degrees or radians.

These differences to not impact the validity of the test results conducted under F2077-03.

(b)(4)

[redacted]

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(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Manufacturing Information

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

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ATTACHMENT B

(b)(4) Testing [redacted]

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(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

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ATTACHMENT C

(b)(4) [redacted]

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(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

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Declaration of Conformity to a Guidance or Special Control

The Renovis S128 ALIF System complies with "Guidance Document Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", June 12, 2007.

This application complies with the elements listed in this guidance document including the following:

- Device design requirements
- Risk analysis for which mitigations, including adequate labeling, are included
- Risks to Health are addressed with appropriate mitigations
- Mechanical Testing to the ASTM standards including the following was completed successfully:
    - Static and dynamic axial compression and compression shear testing
    - Subsidence testing

Demonstration of how the special controls were used to satisfy the requirements of 21 CFR 807.87 are demonstrated or documented in the following documents.

- The design requirements are included as Attachment 012.
- The risk analysis is included as Attachment 013.
- The Risks to Health are addressed in the Instruction for Use (Attachment 016) and the Surgical Manual (Attachment 017)
- Mechanical testing is included in Attachment 021.
-

In addition, the Renovis S128 ALIF System complies with elements of "Guidance for Industry and FDA Staff: Spinal System 510(k)s", May 2004. Although this guidance does not directly include product code MAX, based on previous experience with FDA deficiencies for Surgical Manuals for IBF's, Renovis complies with the following parts:

- Labeling including labels, Instructions for Use and Surgical Manual

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Device Description

Intended Use/Indications for Use

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

Description of technology

The Renovis S128 Anterior Lumber Interbody Fusion (ALIF) System includes the following:

- Implant (cage)
- Screws
- Cover plate

The Renovis S128 ALIF implant (cage) is a hollow structure that can be packed with autogenous bone graft material. It is intended to be used with bone screws and anterior cover plate assembly, and requires no additional supplementary fixation components. The screws protrude through the interbody portion of the device and anchor into the vertebral body to stabilize the interbody device while preventing expulsion of the implant. The Renovis S128 ALIF System contains both fixed and variable angle screw options. The fixed angle screw option provides a tight fit between the screws and the cage. The variable angle screw option provides a slight clearance between the cage and the screws, which allows for a small amount of variable screw angulation. The accompanying cover plate is designed to resist screw back-out and must be used when the screws are implanted. NOTE: The cover plate assembly and screw are part of the implant construct.

The Renovis S128 ALIF System implants are developed for the anterior posterior stabilization of the lumbar spinal column, and are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are available in two lordotic configurations (7° and 12°) of various heights to restore lumbar lordosis and the associated sagittal balance. A large cavity is designed into the body of the cage allowing placement of bone graft material and facilitating fusion. The superior and

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inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants.

The Renovis S128 ALIF System implants are manufactured from either (b)(4) [redacted] or titanium alloy (Ti-6Al-4V). The PEEK component is radiolucent with tantalum markers for visualization in the disc space. The semi-porous titanium version of the cage is manufactured using additive manufacturing. The bone screws and coverplate assembly both manufactured from titanium alloy.

As noted above, the cover plate assembly and screws are part of the implant construct– see Figures 1 – 4 below which demonstrate the screw/cover plate use (the figures are with PEEK implants), Figure 5 is a picture of the Titanium implant, and Figure 6 illustrates the fusion levels.

There are a number of instruments that allows performance of a discectomy, preparation of the disc space, trialing to determine optimal implant width and height, endplate preparation, cage and cover plate assembly, implant insertion and screw insertion.

All components are supplied “NON-STERILE”.

Implants, cover plates and screws are single use and must be sterilized prior to use. Trials and the other instruments are reusable, but also must be sterilized prior to first use, and then cleaned and sterilized prior to subsequent use. Renovis provides the following instruments specific to the Renovis S128 ALIF system:

- Trials
- Sizers
- Implant/cage inserter
- Cover plate inserter

Renovis also provides additional general use manual orthopedic instruments that are not specific to the S128 ALIF system, and recommends that their line of instruments be used. These include: curettes, rasp, chisel, elevator, ronguers, distracters, drill guide and bit; awl, and screw driver.

Implant and Instrument Engineering Drawings

Implant and instrument engineering drawings are included in separate folder in MISC FILES.

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Figure 1

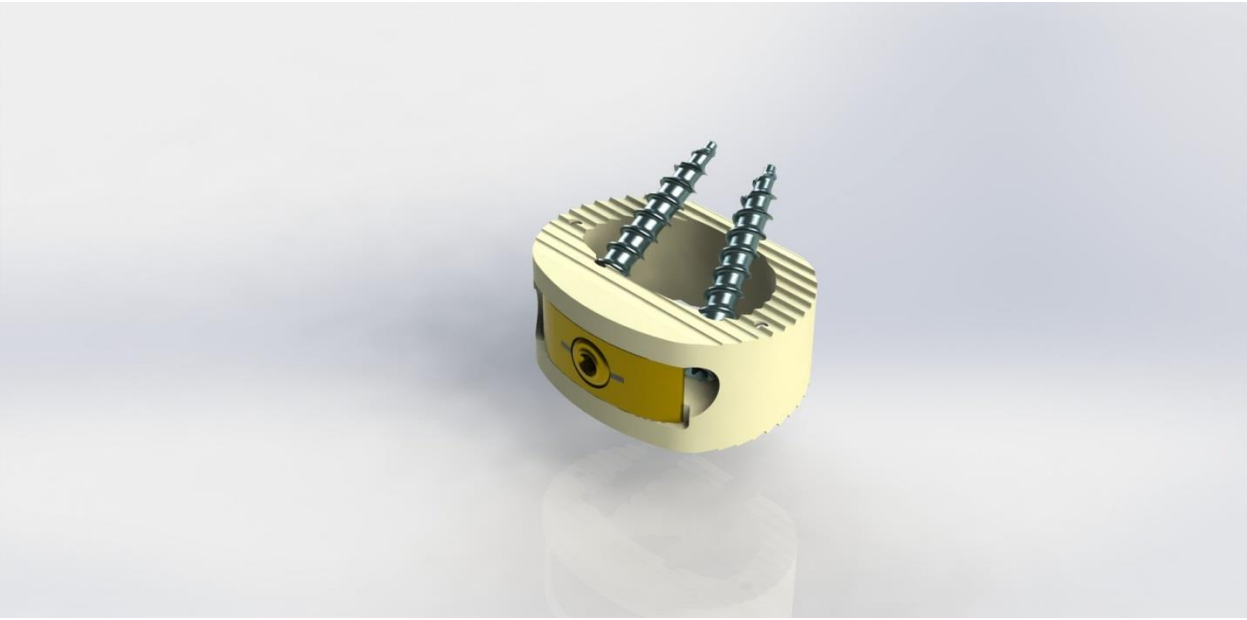

Figure 2

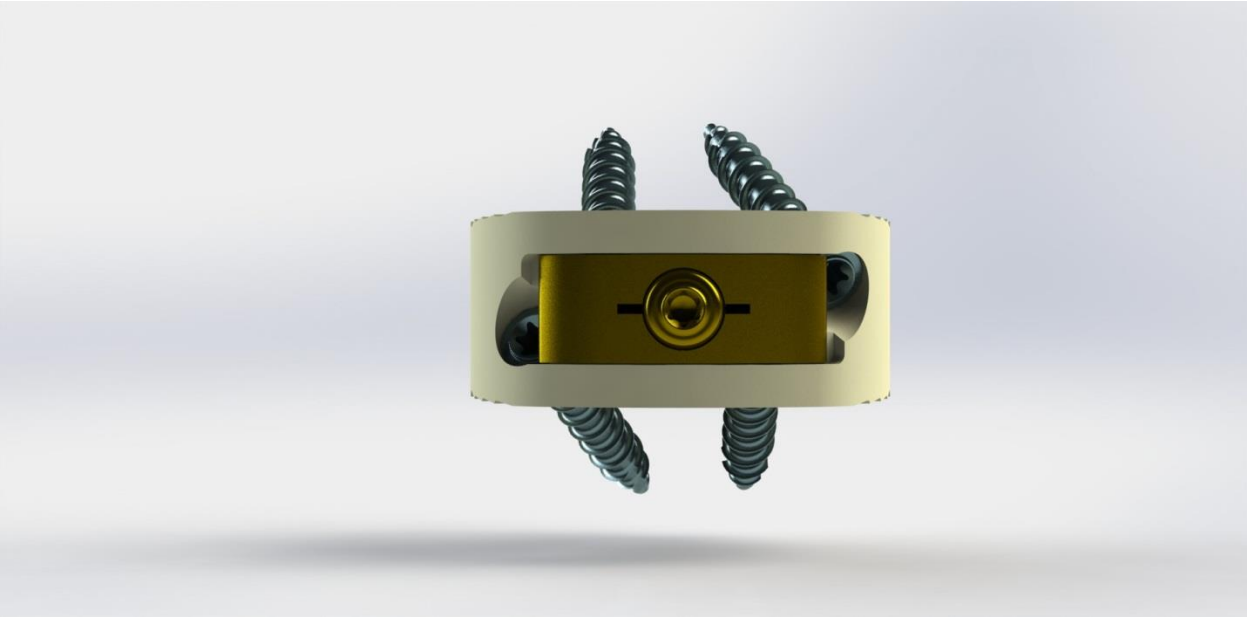

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Figure 3

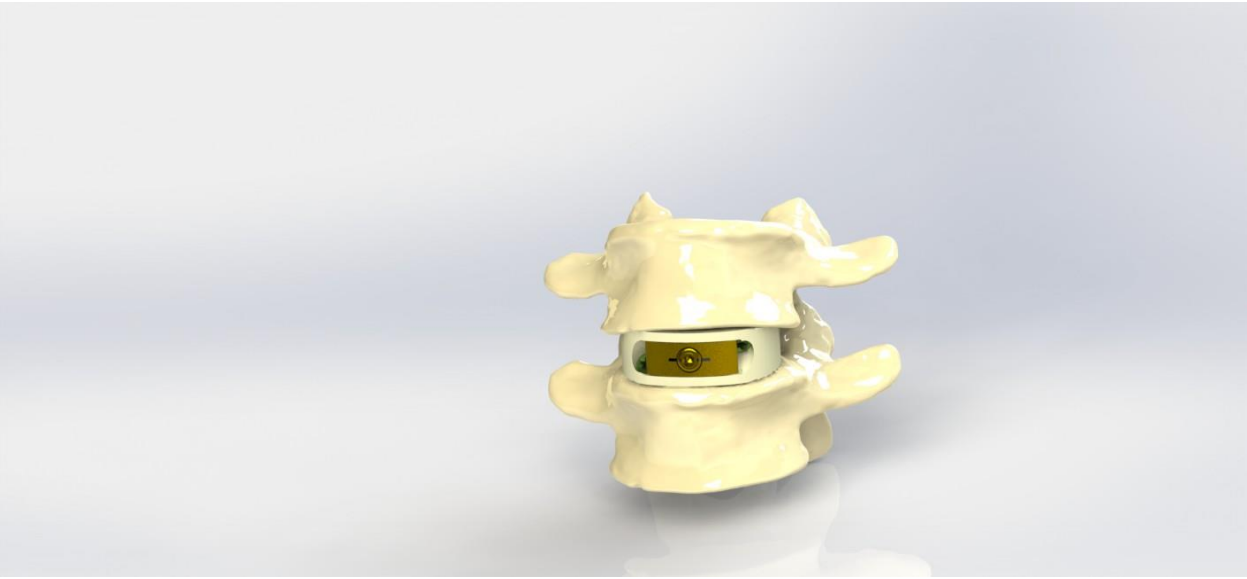

Figure 4

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Figure 5

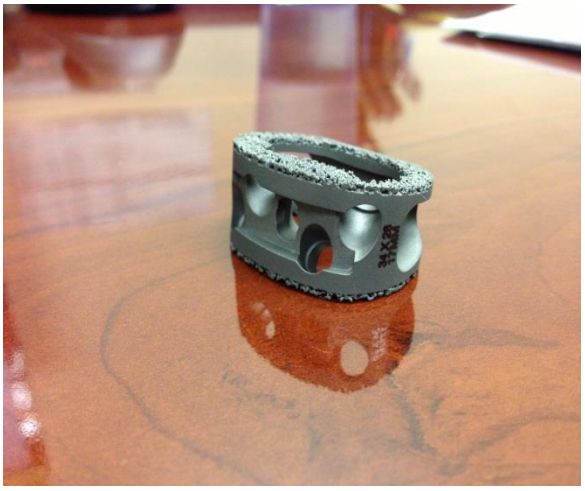
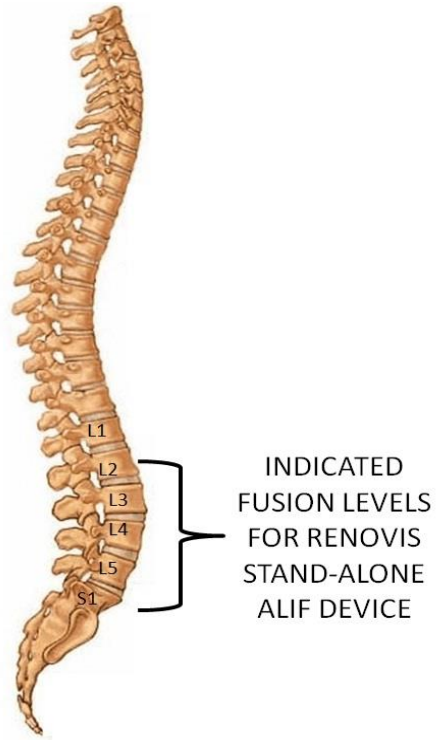


Figure 6



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Materials

- Renovis S128 ALIF implants (cages) are manufactured from either:
  - (b)(4) [redacted]. The PEEK is manufactured per ASTM F2026. Material characterization documentation is available in the (b)(4) [redacted] (b)(4) [redacted]
    - There are three (3) markers (pins) which are manufactured from Tantalum per ASTM F560.
  - Ti6Al4V (titanium alloy). The titanium alloy is manufactured per ASTM F136.
- The screws and the cover plate assembly are manufactured from Ti6Al4V per ASTM F136.
- Renovis S128 ALIF System instrumentation materials and standards are listed on each of the engineering drawings located in MISC FILES.

Geometry and parts numbers

- Implants (cages) are described in Table 1: Titanium in Table 2. Bone graft volume and contact area per endplate are also included.
- Screws are described in Table 3.
- Cover plate assembly is described in Table 4.
- Instruments are described in Table 5.

Table 1: PEEK Cage Geometry

Part Number	Width	Depth	Height	Lordosis	Bone Graft Volume*	(b)(4) [redacted]
1128-302-611	30mm	26mm	11mm	7°	2270mm^3	
1128-302-612	30mm	26mm	12mm	7°	2520 mm^3	
1128-302-613	30mm	26mm	13mm	7°	2770 mm^3	
1128-302-614	30mm	26mm	14mm	7°	3020 mm^3	
1128-302-615	30mm	26mm	15mm	7°	3270 mm^3	
1128-302-616	30mm	26mm	16mm	7°	3530 mm^3	
1128-302-617	30mm	26mm	17mm	7°	3780 mm^3	
1128-302-618	30mm	26mm	18mm	7°	4030 mm^3	
1128-302-619	30mm	26mm	19mm	7°	4280 mm^3	
1128-302-620	30mm	26mm	20mm	7°	4540 mm^3	
1128-302-621	30mm	26mm	21mm	7°	4790 mm^3	
1128-342-811	34mm	26mm	11mm	7°	2940 mm^3	
1128-342-812	34mm	26mm	12mm	7°	3270 mm^3	
1128-342-813	34mm	26mm	13mm	7°	3600 mm^3	
1128-342-814	34mm	26mm	14mm	7°	3920 mm^3	
1128-342-815	34mm	26mm	15mm	7°	4250 mm^3	
1128-342-816	34mm	26mm	16mm	7°	4580 mm^3	

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(b)(4)

1128-342-817	34mm	26mm	17mm	7°	4910 mm^3
1128-342-818	34mm	26mm	18mm	7°	5230 mm^3
1128-342-819	34mm	26mm	19mm	7°	5560 mm^3
1128-342-820	34mm	26mm	20mm	7°	5890 mm^3
1128-342-821	34mm	26mm	21mm	7°	6210 mm^3
1128-383-011	38mm	26mm	11mm	7°	3950 mm^3
1128-383-012	38mm	26mm	12mm	7°	4400 mm^3
1128-383-013	38mm	26mm	13mm	7°	4840 mm^3
1128-383-014	38mm	26mm	14mm	7°	5290 mm^3
1128-383-015	38mm	26mm	15mm	7°	5740 mm^3
1128-383-016	38mm	26mm	16mm	7°	6190 mm^3
1128-383-017	38mm	26mm	17mm	7°	6630 mm^3
1128-383-018	38mm	26mm	18mm	7°	7080 mm^3
1128-383-019	38mm	26mm	19mm	7°	7530 mm^3
1128-383-020	38mm	26mm	20mm	7°	7970 mm^3
1128-383-021	38mm	26mm	21mm	7°	8420 mm^3
1129-302-611	30mm	26mm	11mm	12°	2060 mm^3
1129-302-612	30mm	26mm	12mm	12°	2310 mm^3
1129-302-613	30mm	26mm	13mm	12°	2560 mm^3
1129-302-614	30mm	26mm	14mm	12°	2810 mm^3
1129-302-615	30mm	26mm	15mm	12°	3060 mm^3
1129-302-616	30mm	26mm	16mm	12°	3320 mm^3
1129-302-617	30mm	26mm	17mm	12°	3570 mm^3
1129-302-618	30mm	26mm	18mm	12°	3820 mm^3
1129-302-619	30mm	26mm	19mm	12°	4070 mm^3
1129-302-620	30mm	26mm	20mm	12°	4320 mm^3
1129-302-621	30mm	26mm	21mm	12°	4570 mm^3
1129-342-811	34mm	26mm	11mm	12°	2610 mm^3
1129-342-812	34mm	26mm	12mm	12°	2940 mm^3
1129-342-813	34mm	26mm	13mm	12°	3270 mm^3
1129-342-814	34mm	26mm	14mm	12°	3590 mm^3
1129-342-815	34mm	26mm	15mm	12°	3920 mm^3
1129-342-816	34mm	26mm	16mm	12°	4250 mm^3
1129-342-817	34mm	26mm	17mm	12°	4570 mm^3
1129-342-818	34mm	26mm	18mm	12°	4900 mm^3
1129-342-819	34mm	26mm	19mm	12°	5230 mm^3
1129-342-820	34mm	26mm	20mm	12°	5560 mm^3
1129-342-821	34mm	26mm	21mm	12°	5880 mm^3
1129-383-011	38mm	26mm	11mm	12°	3450 mm^3
1129-383-012	38mm	26mm	12mm	12°	3900 mm^3
1129-383-013	38mm	26mm	13mm	12°	4340 mm^3
1129-383-014	38mm	26mm	14mm	12°	4790 mm^3
1129-383-015	38mm	26mm	15mm	12°	5240 mm^3

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(b)(4)

1129-383-016	38mm	26mm	16mm	12°	5680 mm^3	[redacted]
1129-383-017	38mm	26mm	17mm	12°	6130 mm^3	[redacted]
1129-383-018	38mm	26mm	18mm	12°	6580 mm^3	[redacted]
1129-383-019	38mm	26mm	19mm	12°	7030 mm^3	[redacted]
1129-383-020	38mm	26mm	20mm	12°	7470 mm^3	[redacted]
1129-383-021	38mm	26mm	21mm	12°	7920 mm^3	[redacted]

*estimate - rounded down to closest 10mm^3; ** estimate – rounded down to closest 10mm

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Table 2: Titanium Cage Geometry

Part Number	Width	Depth	Height	Lordosis	Bone Graft Volume*	(b)(4)
1131-302-611	30mm	26mm	11.25mm	7°	2270mm^3	[redacted]
1131-302-612	30mm	26mm	12.25mm	7°	2520 mm^3	
1131-302-613	30mm	26mm	13.25mm	7°	2770 mm^3	
1131-302-614	30mm	26mm	14.25mm	7°	3020 mm^3	
1131-302-615	30mm	26mm	15.25mm	7°	3270 mm^3	
1131-302-616	30mm	26mm	16.25mm	7°	3530 mm^3	
1131-302-617	30mm	26mm	17.25mm	7°	3780 mm^3	
1131-302-618	30mm	26mm	18.25mm	7°	4030 mm^3	
1131-302-619	30mm	26mm	19.25mm	7°	4280 mm^3	
1131-302-620	30mm	26mm	20.25mm	7°	4540 mm^3	
1131-302-621	30mm	26mm	21.25mm	7°	4790 mm^3	
1131-342-811	34mm	28mm	11.25mm	7°	2940 mm^3	
1131-342-812	34mm	28mm	12.25mm	7°	3270 mm^3	
1131-342-813	34mm	28mm	13.25mm	7°	3600 mm^3	
1131-342-814	34mm	28mm	14.25mm	7°	3920 mm^3	
1131-342-815	34mm	28mm	15.25mm	7°	4250 mm^3	
1131-342-816	34mm	28mm	16.25mm	7°	4580 mm^3	
1131-342-817	34mm	28mm	17.25mm	7°	4910 mm^3	
1131-342-818	34mm	28mm	18.25mm	7°	5230 mm^3	
1131-342-819	34mm	28mm	19.25mm	7°	5560 mm^3	
1131-342-820	34mm	28mm	20.25mm	7°	5890 mm^3	
1131-342-821	34mm	28mm	21.25mm	7°	6210 mm^3	
1131-383-011	38mm	30mm	11.25mm	7°	3950 mm^3	
1131-383-012	38mm	30mm	12.25mm	7°	4400 mm^3	
1131-383-013	38mm	30mm	13.25mm	7°	4840 mm^3	
1131-383-014	38mm	30mm	14.25mm	7°	5290 mm^3	
1131-383-015	38mm	30mm	15.25mm	7°	5740 mm^3	
1131-383-016	38mm	30mm	16.25mm	7°	6190 mm^3	
1131-383-017	38mm	30mm	17.25mm	7°	6630 mm^3	
1131-383-018	38mm	30mm	18.25mm	7°	7080 mm^3	
1131-383-019	38mm	30mm	19.25mm	7°	7530 mm^3	
1131-383-020	38mm	30mm	20.25mm	7°	7970 mm^3	
1131-383-021	38mm	30mm	21.25mm	7°	8420 mm^3	
1133-302-611	30mm	26mm	11.25mm	12°	2060 mm^3	
1133-302-612	30mm	26mm	12.25mm	12°	2310 mm^3	
1133-302-613	30mm	26mm	13.25mm	12°	2560 mm^3	
1133-302-614	30mm	26mm	14.25mm	12°	2810 mm^3	
1133-302-615	30mm	26mm	15.25mm	12°	3060 mm^3	
1133-302-616	30mm	26mm	16.25mm	12°	3320 mm^3	

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(b)(4)

1133-302-617	30mm	26mm	17.25mm	12°	3570 mm^3
1133-302-618	30mm	26mm	18.25mm	12°	3820 mm^3
1133-302-619	30mm	26mm	19.25mm	12°	4070 mm^3
1133-302-620	30mm	26mm	20.25mm	12°	4320 mm^3
1133-302-621	30mm	26mm	21.25mm	12°	4570 mm^3
1133-342-811	34mm	28mm	11.25mm	12°	2610 mm^3
1133-342-812	34mm	28mm	12.25mm	12°	2940 mm^3
1133-342-813	34mm	28mm	13.25mm	12°	3270 mm^3
1133-342-814	34mm	28mm	14.25mm	12°	3590 mm^3
1133-342-815	34mm	28mm	15.25mm	12°	3920 mm^3
1133-342-816	34mm	28mm	16.25mm	12°	4250 mm^3
1133-342-817	34mm	28mm	17.25mm	12°	4570 mm^3
1133-342-818	34mm	28mm	18.25mm	12°	4900 mm^3
1133-342-819	34mm	28mm	19.25mm	12°	5230 mm^3
1133-342-820	34mm	28mm	20.25mm	12°	5560 mm^3
1133-342-821	34mm	28mm	21.25mm	12°	5880 mm^3
1133-383-011	38mm	30mm	11.25mm	12°	3450 mm^3
1133-383-012	38mm	30mm	12.25mm	12°	3900 mm^3
1133-383-013	38mm	30mm	13.25mm	12°	4340 mm^3
1133-383-014	38mm	30mm	14.25mm	12°	4790 mm^3
1133-383-015	38mm	30mm	15.25mm	12°	5240 mm^3
1133-383-016	38mm	30mm	16.25mm	12°	5680 mm^3
1133-383-017	38mm	30mm	17.25mm	12°	6130 mm^3
1133-383-018	38mm	30mm	18.25mm	12°	6580 mm^3
1133-383-019	38mm	30mm	19.25mm	12°	7030 mm^3
1133-383-020	38mm	30mm	20.25mm	12°	7470 mm^3
1133-383-021	38mm	30mm	21.25mm	12°	7920 mm^3

*estimate - rounded down to closest 10mm^3; ** estimate – rounded down to [redacted]

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Table 3: Screw Geometry

Part Number	Description	Shaft Length	(b)(4) [redacted]	Thread OD	(b)(4) [redacted]
1128-453-020	4.5mm Variable Screw	20mm		4.5mm	
1128-453-025	4.5mm Variable Screw	25mm		4.5mm	
1128-453-030	4.5mm Variable Screw	30mm		4.5mm	
1128-453-035	4.5mm Variable Screw	35mm		4.5mm	
1129-453-020	4.5mm Constrained Screw	20mm		4.5mm	
1129-453-025	4.5mm Constrained Screw	25mm		4.5mm	
1129-453-030	4.5mm Constrained Screw	30mm		4.5mm	
1129-453-035	4.5mm Constrained Screw	35mm		4.5mm	
1129-503-020	5.0mm Constrained Screw	20mm		5.0mm	
1129-503-025	5.0mm Constrained Screw	25mm		5.0mm	
1129-503-030	5.0mm Constrained Screw	30mm		5.0mm	
1129-503-035	5.0mm Constrained Screw	35mm		5.0mm	
1130-503-020	5.0mm Rescue Screw	20mm		5.0mm	
1130-503-025	5.0mm Rescue Screw	25mm		5.0mm	
1130-503-030	5.0mm Rescue Screw	30mm		5.0mm	
1130-503-035	5.0mm Rescue Screw	35mm		5.0mm	

Table 4: Cover Plate Assembly Geometry

Part Number	Height	Width	(b)(4) [redacted]
1128-003-001	8.3mm	22mm	

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Table 5: Instrument Listing

Part Number	Description	Functionality
2128-001-001	Implant Inserter	Insert Cage
2128-001-002	Distractor Implant Inserter Assembly	Insert Cage
2128-001-003	Implant Impactor	Position Cage
2128-001-004	Cover Plate Inserter Assembly	Insert and lock Coverplate
2128-001-005	Trial Implant/Bullet Distractor Inserter	Insert and remove Trial and Bullet Nose Distractors
2128-001-006	Rasp	Disc preparation
2128-001-007	Adjustable Drill Guide	Screw hole preparation
2128-001-008	Captured Spring Loaded Awl	Screw hole preparation
2128-001-009	Cover Plate Driver	Insert, lock and possibly remove Coverplate
2128-001-010	Screw Driver with Universal Joint	Insert and remove screws
2128-001-011	Screw Driver with Solid Shaft	Insert and remove screws
2128-001-012	Awl with Universal Joint	Screw hole preparation
2128-001-013	Modular Drill Bit 3.0mm Diameter 8mm Engagement Length	Screw Hole Preparation
2128-001-014	Modular Flexible Drill Shaft	Screw Hole Preparation
2128-001-015	Small Cup Curette	Disc preparation
2128-001-016	Large Cup Curette	Disc preparation
2128-001-017	Small Up Angled Cup Curette	Disc preparation
2128-001-018	Ringed Curette	Disc preparation
2128-001-019	Chisel	Disc preparation
2128-001-020	23mm Sharp Cobb	Disc preparation
2128-001-021	17mm Sharp Cobb	Disc preparation
2128-001-023	Small Sypert Rongeur	Disc preparation
2128-001-024	Large Sypert Rongeur	Disc preparation
2128-001-025	3mm Pituitary Rongeur	Disc preparation
2128-001-026	5mm Pituitary Rongeur	Disc preparation
2128-001-027	Small Kerrison Rongeur	Disc preparation
2128-001-028	Large Kerrison Rongeur	Disc preparation
2128-001-029	Small Modular Handle	Handle for various instruments
2128-001-030	Large Modular Handle	Handle for various instruments
2128-001-031	Large Threaded Handle	Handle for various instruments
2128-001-032	Angled Implant Inserter	Insert Cage
2128-001-033	Angled Cover Plate Inserter	Insert Cover plate
2128-001-034	Modular Screw Driver Bit	Insert and remove screws
2128-001-035	Packing Block	Hold cage to facilitate autograft addition.
2128-001-036	Long Scalpel Handle	Disc preparation
2128-003-026	Small Paddle Sizer	Implant determination
2128-003-428	Medium Paddle Sizer	Implant determination

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2128-003-830	Large Paddle Sizer	Implant determination
2128-002-009	9mm Bullet Nose Distractor	Disc space distraction
2128-002-011	11mm Bullet Nose Distractor	Disc space distraction
2128-002-013	13mm Bullet Nose Distractor	Disc space distraction
2128-002-015	15mm Bullet Nose Distractor	Disc space distraction
2128-002-017	17mm Bullet Nose Distractor	Disc space distraction
2128-002-019	19mm Bullet Nose Distractor	Disc space distraction
2128-002-021	21mm Bullet Nose Distractor	Disc space distraction
2128-302-611	11mm Trial, 30x26 7°	Trialing
2128-302-612	12mm Trial, 30x26 7°	Trialing
2128-302-613	13mm Trial, 30x26 7°	Trialing
2128-302-614	14mm Trial, 30x26 7°	Trialing
2128-302-615	15mm Trial, 30x26 7°	Trialing
2128-302-616	16mm Trial, 30x26 7°	Trialing
2128-302-617	17mm Trial, 30x26 7°	Trialing
2128-302-618	18mm Trial, 30x26 7°	Trialing
2128-302-619	19mm Trial, 30x26 7°	Trialing
2128-302-620	20mm Trial, 30x26 7°	Trialing
2128-302-621	21mm Trial, 30x26 7°	Trialing
2128-342-811	11mm Trial, 34x28 7°	Trialing
2128-342-812	12mm Trial, 34x28 7°	Trialing
2128-342-813	13mm Trial, 34x28 7°	Trialing
2128-342-814	14mm Trial, 34x28 7°	Trialing
2128-342-815	15mm Trial, 34x28 7°	Trialing
2128-342-816	16mm Trial, 34x28 7°	Trialing
2128-342-817	17mm Trial, 34x28 7°	Trialing
2128-342-818	18mm Trial, 34x28 7°	Trialing
2128-342-819	19mm Trial, 34x28 7°	Trialing
2128-342-820	20mm Trial, 34x28 7°	Trialing
2128-342-821	21mm Trial, 34x28 7°	Trialing
2128-383-011	11mm Trial, 38x28 7°	Trialing
2128-383-012	12mm Trial, 38x30 7°	Trialing
2128-383-013	13mm Trial, 38x30 7°	Trialing
2128-383-014	14mm Trial, 38x30 7°	Trialing
2128-383-015	15mm Trial, 38x30 7°	Trialing
2128-383-016	16mm Trial, 38x30 7°	Trialing
2128-383-017	17mm Trial, 38x30 7°	Trialing
2128-383-018	18mm Trial, 38x30 7°	Trialing
2128-383-019	19mm Trial, 38x30 7°	Trialing
2128-383-020	20mm Trial, 38x30 7°	Trialing
2128-383-021	21mm Trial, 38x30 7°	Trialing
2129-302-611	11mm Trial, 30x26 12°	Trialing
2129-302-612	12mm Trial, 30x26 12°	Trialing

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2129-302-613	13mm Trial, 30x26 12°	Trialing
2129-302-614	14mm Trial, 30x26 12°	Trialing
2129-302-615	15mm Trial, 30x26 12°	Trialing
2129-302-616	16mm Trial, 30x26 12°	Trialing
2129-302-617	17mm Trial, 30x26 12°	Trialing
2129-302-618	18mm Trial, 30x26 12°	Trialing
2129-302-619	19mm Trial, 30x26 12°	Trialing
2129-302-620	20mm Trial, 30x26 12°	Trialing
2129-302-621	21mm Trial, 30x26 12°	Trialing
2129-342-811	11mm Trial, 34x28 12°	Trialing
2129-342-812	12mm Trial, 34x28 12°	Trialing
2129-342-813	13mm Trial, 34x28 12°	Trialing
2129-342-814	14mm Trial, 34x28 12°	Trialing
2129-342-815	15mm Trial, 34x28 12°	Trialing
2129-342-816	16mm Trial, 34x28 12°	Trialing
2129-342-817	17mm Trial, 34x28 12°	Trialing
2129-342-818	18mm Trial, 34x28 12°	Trialing
2129-342-819	19mm Trial, 34x28 12°	Trialing
2129-342-820	20mm Trial, 34x28 12°	Trialing
2129-342-821	21mm Trial, 34x28 12°	Trialing
2129-383-011	11mm Trial, 38x28 12°	Trialing
2129-383-012	12mm Trial, 38x30 12°	Trialing
2129-383-013	13mm Trial, 38x30 12°	Trialing
2129-383-014	14mm Trial, 38x30 12°	Trialing
2129-383-015	15mm Trial, 38x30 12°	Trialing
2129-383-016	16mm Trial, 38x30 12°	Trialing
2129-383-017	17mm Trial, 38x30 12°	Trialing
2129-383-018	18mm Trial, 38x30 12°	Trialing
2129-383-019	19mm Trial, 38x30 12°	Trialing
2129-383-020	20mm Trial, 38x30 12°	Trialing
2129-383-021	21mm Trial, 38x30 12°	Trialing

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Design Requirements

As specified in Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 2007, the description of design requirements for the Renovis ALIF are described in the column Requirements, below. The PEEK and Titanium implants are described separately.

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

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Risk Analysis

As specified in Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 2007, the risk analysis for the Renovis S128 ALIF System is described below.

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(b)(4) Risk Analysis

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Substantial Equivalence Discussion

Tables 1 compares the Indications for Use of the predicate devices. Table 2 compares the implant, screw and cover plates (as applicable). Table 3 compares the instruments provided with each system.

Table 1 Indications for Use

Device	Indications for use
Renovis S128 ALIF System	The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The Renovis S128 ALIF System is a stand-alone device and is intended to be used with thecover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.
Blackstone Orthofix Pillar	When used as an intervertebral body fusion device, the PILLARTM Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S 1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous nonfusion surgery at the involved level(s). (b)(4) [redacted]

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	Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PILLARTM Spacer System. (b)(4) [redacted]
K2M Chesapeake **K092211**	The Chesapeake Spinal System is intended to be used with the bone screws provided and requires no additional supplementary fixation. The Chesapeake implants are intended for spinal fusion procedures in skeletally mature patients who have had six months of non-operative treatment. When used as intervertebral body fusion devices, the implants are indicated for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studied. This device is intended to be used with autogenous bone graft.

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Lanx, Inc. **Intervertebral Body Fusion Device** **K073144 – PEEK implants** **Fusion System** **K083815 – Ti cage** **Fusion System** **K102738- SA implant with Ti components** **Lateral – SA System** **K123767- additional PEEK cages and Ti screw fixation configurations**	**K073144:** The Lanx Intervertebral Body Fusion Device ("Lanx Fusion System") is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S 1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Lanx Fusion System is to be implanted via an anterior or posterior approach and is to be combined with supplemental fixation. Approved supplemental fixation systems include the Lanx Spinal Fixation System. **K083815:** When used as a lumbar intervertebral body fusion device, the Lanx Intervertebral Body/VBR Fusion System ("Lanx Fusion System') is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD') at one or two contiguous spinal levels from L2-SJ. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of nonoperative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Lanx Fusion System is to be implanted via an anterior or posterior approach and is to be combined with supplemental fixation. **K102738** – Same as K083815, but includes "Approved supplemental fixation systems include the Lanx Spinal Fixation System. The Lanx SA standalone interbody implants, when used with the integrated fixation screws, do not require use of supplemental fixation." **K123767** – Same as K102738 but includes "The Lanx Lateral-SA implants are to be used with supplemental fixation.
Calvary Spine **Petra PLIF Cage System**	The Petra PLIF Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous

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K082260	levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Petra PLIF Cage implants are to be used with autogenous bone graft and implanted via an open posterior approach. The Petra PLIF Cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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Table 2 Implant, screw and cover plate*

	Renovis S128 ALIF System	Blackstone (Orthofix) Pillar K081177	K2M Chesapeake K092211	Lanx Lateral SA System K123767 Fusions System K102738 Fusion System K083815 Intervertebral Body Fusion Device K073144	Calvary Spine Petra PLIF Cage System K082260
				Picture not available	
Implant Material	(b)(4) PEEK Titanium alloy	(b)(4) PEEK	PEEK	(b)(4) PEEK Titanium alloy	(b)(4) PEEK
Dimensions in mm A/P M/L H	 26, 28, 30 30, 34, 38 11 – 21 Δ1mm	 28, 32 37, 40, 43 12.5 – 20 Δ2mm	 24, 28, 30 30, 36, 40 11-19 Δ2mm	 16, 18, 22, 26 25 to 60 6-16	Crescent (above) 13 x 27 Straight – 11x30 7-15 Δ1mm
Foot print	30 x 26D 34 x 28D	33 x 28D 27 x 28D	24 x 30D 28 x 36D	Not reported	Crescent (above) 13 x 27

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	38 x 30D	40 x 32D 43 x 32D	30 x 40 D		Straight – 11x30
Ridges	Yes	Yes	Yes	Yes	Yes
Lordosis	7°, 12°	7°, 12°	10^0, 15^0	0^0, 8^0	8^0
Screw material	Titanium alloy Ti-6Al-4V per ASTM F136	Titanium alloy Ti-6Al-4V per ASTM F136	Titanium alloy	Titanium alloy Ti-6Al-4V per ASTM F136	NA
Number of screws required	4	4	3	K102738 - # unk K123767 - # unk	NA
Screw Diameter (mm)	4.5, 5.0	5.0, 5.5	5.5	Unknown	NA
Screw Length (mm)	20, 25, 30, 35	20, 25, 30, 35	20, 25, 30	Unknown	NA
Cover plate	Titanium	Titanium	None	Unknown	NA
Marker material	Tantalum	Tantalum	Tantalum	Tantalum	Tantulum
Bone graft volume	2270 – 7920 mm^3	Not available	Not available	Not available	Not available
End plate coverage	340 – 360 mm^2	Not available	Not available	Not available	90 mm^2
Fixation	May be standalone or with FDA cleared supplemental	May be stand alone or SFS spinal fixation (K994217)	Stand alone	Standalone or with FDA cleared supplemental depending on the K#.	Requires supplemental fixation

*510(k) Summaries did not provide complete information, and available marketing information was accessed for specifications

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Table 3 Device Specific instruments provided

Renovis S128 ALIF System	Blackstone (Orthofix) Pillar SA K081177
• Sizers/Trials • Implant Inserter/Impactor • Cover Plate Inserter	• Trials • Implant/Trial Inserter • Cover plate Inserter

Substantial Equivalence Discussion including similarities and differences

(b)(4)

[redacted]

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(b)(4) Substantial Equivalence

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Conclusion

Based upon the same or similar intended use, similar design, function, technology, materials and mechanical testing performance, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

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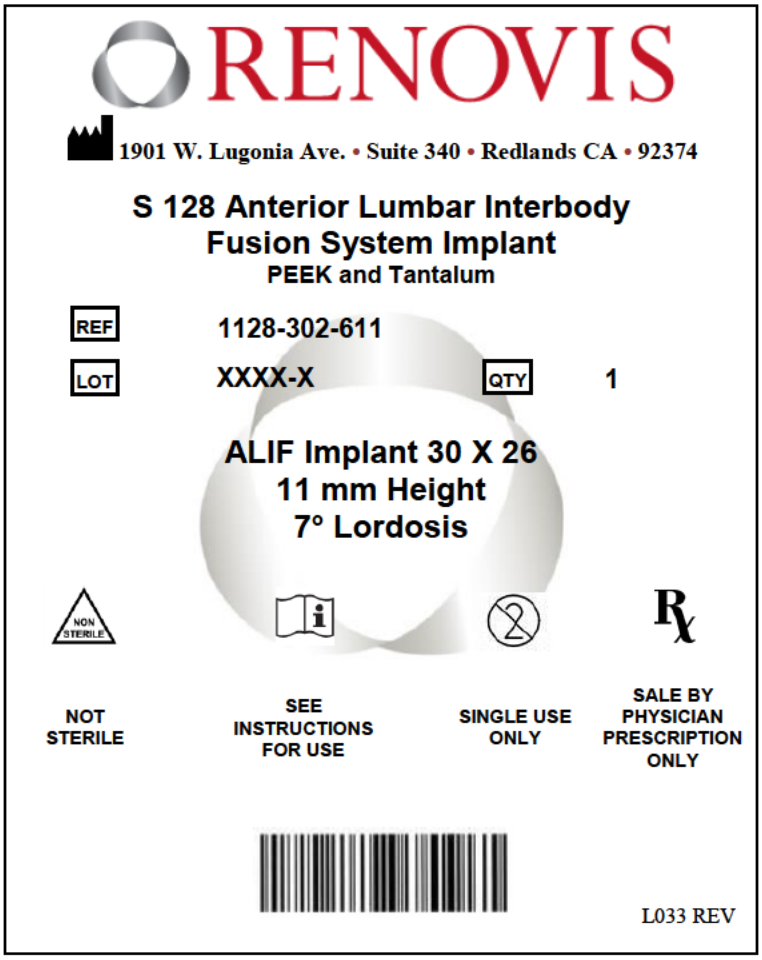
Labeling

Labels

Below are examples of draft examples of labels for the implants and instruments. For Label 1 below, each field will be completed per the appropriate implant.

Label 1 Example of implant label



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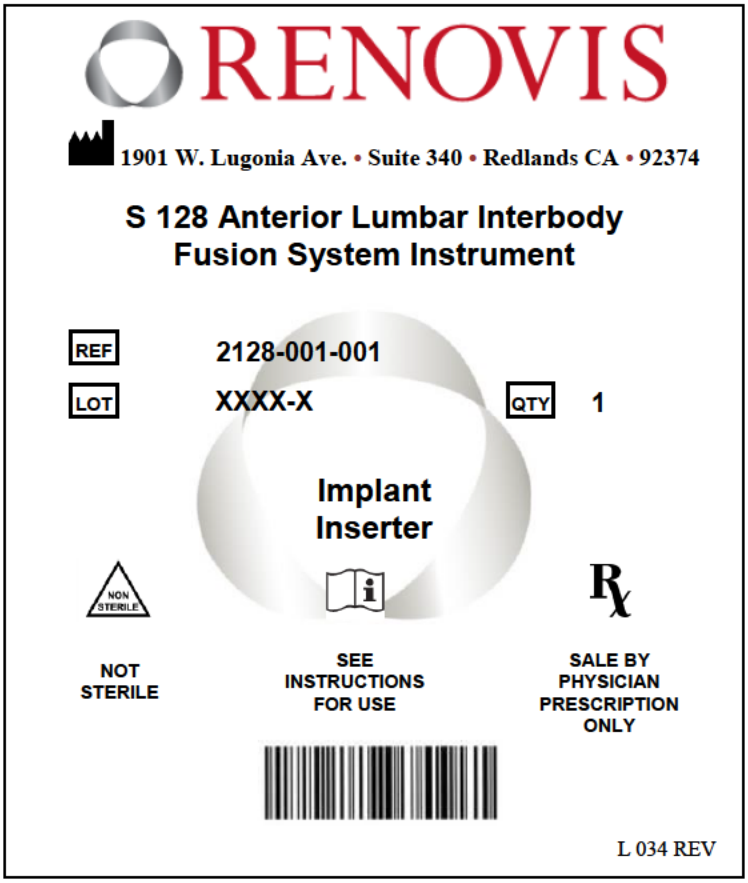
Label 2 **Example of Instrument Label**



Instructions for Use

The Instructions for Use for the Renovis S128 ALIF System is included as Attachment 016. A Word copy is included in MISC FILES.

Surgical Manual

The Surgical Manual is included as Attachment 017. A Word copy is included in MISC FILES.

Instrument Instructions for Use

The Instructions for Use for the instruments is included as Attachment 018. This set of instructions is used for all Renovis instruments, not just the instruments specific to the S128 ALIF system. A Word copy is included in MISC FILES.

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

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RENOVIS

S 128 Anterior Lumbar Interbody Fusion (ALIF) System

4128-001

Rev. A (Draft)

Instructions For Use

DESCRIPTION:

The S128 Anterior Lumbar Interbody Fusion (ALIF) System is an internal spinal fixation system comprised of PEEK or Titanium Interbody cages, Titanium screws and Titanium Cover Plate assemblies. The system also includes several instruments that assist in proper implantation; these instruments include: Trials, Sizers, Cage Inserters, and Cover Plate Inserters.

IMPORTANT NOTE:

This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

MATERIAL:

All implant components of the S128 Anterior Lumbar Interbody Fusion (ALIF) System are made of the following materials:

1. Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136
2. Polyetheretherketone (PEEK): according to ASTM F-2026
3. Tantalum: according to ISO 13782-1996 and ASTM F-560

INDICATIONS FOR USE:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

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The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

GENERAL CONDITIONS OF USE:

The safe implantation of Anterior Lumbar Interbody Fusion (ALIF) Systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the S128 Anterior Lumbar Interbody Fusion (ALIF) System should be performed only by experienced spinal surgeons with specific training in the use of interbody fusion. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The S128 Anterior Lumbar Interbody Fusion (ALIF) System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. Under no circumstances should any component of the S128 Anterior Lumbar Interbody Fusion (ALIF) System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. After spinal fusion occurs, these devices serve no functional purpose and may be removed. The decision to explant the surgical devices is made between the surgeon and the patient with due regard to the risks associated with a second surgery compared to the benefits of such. The S128 ALIF System has been tested as a standalone construct.

CONTRAINDICATIONS:

Contraindications to using the S128 Anterior Lumbar Interbody Fusion (ALIF) System are similar to those of other Anterior Lumbar Interbody Fusion (ALIF) Systems and consist of the following:

1. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
2. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
3. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the implant without risk of impairment to anatomical structures or physiologic performance.
4. Patients with a suspected or documented metal allergy or intolerance.
5. Inadequate tissue coverage over the operative site.
6. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
7. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

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POTENTIAL RISKS:

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

PATIENT SELECTION:

The following factors can be extremely important to the eventual success of the procedure:

1. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

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5. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

WARNINGS AND CAUTIONS:

Only experienced spinal surgeons with specific training in the use of interbody fusion system should implant interbody fusion devices, because this is a technically demanding procedure presenting a risk of serious injury to the patient

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, share, and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. Single use only. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
3. Correct implant handling is vital. These devices may not be contoured. Avoid any notching, scratching or reverse bending of the devices when handling. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected.
4. Non-sterile; the S128 Anterior Lumbar Interbody Fusion System implants and instruments are provided non-sterile, and therefore, must be sterilized before each use.
5. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
6. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
7. Renovis Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The implants in the S128 ALIF are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:
    a. Movement of ferromagnetic components through magnetically induced force and torque.
    b. Localized heating of components caused by radio frequency induction heating.
    c. Image artifacts created by interaction between metallic components and the magnetic field.

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ADVERSE AFFECTS:

In addition to the obvious risk that any orthopedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget's disease. Patients suffering from Paget's disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While formation wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
3. Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Tivanium™ Ti-6AL-4V Alloy) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

HANDLING OF IMPLANTS

1. Receipt – Carefully unwrap and handle non-sterilized implants and instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration.
2. Transport - Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.
3. Storage - Store implants or instruments prior to use in such a manner as to maintain the device's surface finish or configuration, or both. Stock Rotation—The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility, and configuration. Keep implants made of different metals separated. Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.

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4. Traceability - Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting, and/or possible traceability to the manufacturer.

CLEANING:
All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device. Renovis Instrument IFU 4001-001 provides more detailed information about proper cleaning of the instruments in the S128 ALIF System.

STERILITY:
Renovis S128 ALIF Implants are provided clean but non-sterile, and must be sterilized before use. Sterilization is recommended as follows:

Cycle	Dynamic-air-removal Steam
Preconditioning Pulses	4
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	40 Minutes

These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and a new cycle must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.
Do not sterilize implants in contact with instruments or implants of other materials. Metallic oxide could transfer to the implant, initiating an unacceptable conditioning.

The packaging in which non-sterile implants are supplied should not be used for sterilization methods in the hospital. The implants should be sterilized in the provided caddies. Repackaged and re-sterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

References: References to relevant literature including the Surgical Technique Manual may be obtained by calling Renovis Surgical Technologies, LLC. at +1.909.557.2360.

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Caution: Federal Law USA restricts this device to sale by or on the order of a physician.

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Recommendations for the Care and Handling for Renovis Surgical Technologies
Surgical Instruments and Instrument Cases

DESCRIPTION

Renovis instrumentation consists of devices and their accessories used in surgical procedures. Before using Renovis instrumentation for any surgical procedure, familiarity with, and attention to the appropriate, recommended surgical technique is imperative. Renovis instrumentation should only be used in combination with other Renovis products.

Renovis instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and listed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility. Instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below.

DISCLAIMER

Renovis instrument cases are intended to protect instrumentation and facilitate the sterilization process by allowing steam penetration and drying. Renovis has verified through laboratory testing that our instrument cases are suitable for the specific sterilization cycles for which they have been tested. Heath care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility. Testing should be conducted in health care facility to assure that conditions essential to sterilization can be achieved. Renovis and its distributors do not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical device supplied by Renovis that should have been cleaned and sterilized by the end user. All instruments are to be examined for wear and damage prior to surgery.

CLEANING AND DECONTAMINATION

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

Renovis rigid instrument cases may be washed and/or disinfected by using an automated washer-disinfection unit utilizing thermal disinfection. Temperatures, cycles, and disinfectant type used as instructed by manufacturer of washer-disinfection unit.

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1. **Decontamination:** Saturate the surface completely with full strength disinfectant/cleaner* (e.g. ENZOL® Enzymatic Detergent). Fully immerse the devices and allow them to soak for a minimum of 5 minutes.
2. **Pre-Cleaning:** Disassemble devices where applicable. The majority of the surgical instruments and trial devices are simply constructed and will not require disassembly. However, some of the more complex instruments are made of several components and these should be disassembled into their individual parts. Prepare a room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and remove gross contaminants by thoroughly brushing devices with a soft bristled brush ensuring all hard to reach areas are accessed.
3. **Washing:** Immerse devices in the ultrasonic washer/cleaner with room temperature neutral pH enzymatic cleaner* (e.g. ENZOL® Enzymatic Detergent) and sonicate for a minimum of 10 minutes. For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level and concentration. When using mechanical washers, make sure the instruments are secured in place and do not touch or overlap.
4. **Rinsing:** Thoroughly rinse the devices with deionized or distilled water for a minimum of 2 minutes. Repeat rinsing a total of three (3) times.
5. **Drying:** Allow devices to air dry for a minimum of 20 minutes prior to inspection and sterilization preparation. Instruments must be thoroughly dried to remove residual moisture before they are stored.
6. **Preparation and Assembly:** After cleaning/disinfection, the disassembled instruments should be reassembled and visually inspected. Check for misalignment, burrs, bent, or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Place instruments into appropriate configuration within instrument case and wrap with protective sterilization wrap according to AAMI / AORN guidelines.

* Do not use high acidic (pH <4) or high alkaline (pH >10) products for disinfection or cleaning, since these can corrode metal, cause discoloration or stress fractures. Renovis has qualified the above cleaning method with the provided solution examples, for a 3 Spore Log Reduction (SLR). Other cleaning/disinfection methods may also be suitable; however, individuals or hospitals not using the recommended method are advised to validate any alternate method using appropriate laboratory techniques.

CARE AND HANDLING OF INSTRUMENTS

1. **General** – Surgical instruments and instrument cases are susceptible to damage from prolonged use, and through misuse or rough handling. Care must be taken to avoid compromising their performance. To minimize damage, conduct the following:
   - Inspect instrument cases and instruments for damage when received and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned, and those that need repair returned for servicing.
   - Only use an instrument for its intended purpose.
   - When handling sharp instruments use extreme caution to avoid injury. Consult with an infection control practitioner to develop safety procedures appropriate for all levels of direct instrument contact.

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- Instruments designated as "Single Use Only" are to be disposed of immediately after use. Reuse can cause small defects and internal stress patterns which may result in premature breakage.

2. **General Cleaning** – Clean instruments as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate enzymatic detergent to delay drying. Wash all instruments whether or not they were used or were inadvertently contacted with blood. Loosen and/or disassemble instruments with removable parts.
3. **Ultrasonic Cleaners** – can be used with hot water per the manufacturers' recommended temperature, however, room temperature was qualified. Be aware that loading patterns, water temperature, and other external factors may change the effectiveness of the equipment.

RESPONSIBILITIES OF THE USER

General – Heath care personnel are ultimately responsible for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterilization processing and sterility maintenance in their particular health care facility.
Sterility – Users should conduct testing in health care facility to assure that conditions essential to sterilization can be achieved.

STORAGE AND SHELF LIFE

Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be taken in handling wrapped cases to prevent damage to the barrier. The health care facility should establish a shelf life for wrapped instruments cases, based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling.

Sterility: Renovis Instruments are provided non-sterile. Sterilization is recommended as follows:

Cycle	Dynamic-air-removal Steam
Preconditioning Pulses	4
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	40 Minutes

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These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and a new cycle must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

The packaging in which non-sterile instruments are supplied should not be used for sterilization methods in the hospital. Repackaged and resterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

References: References to relevant literature may be obtained by calling Renovis Surgical Technologies, LLC. at +1-909-557-2360.

Caution: Federal Law USA restricts this device to sale by or on the order of a physician.

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CE
CE
0086

For Single-Use Instruments Only.

The CE marks above are valid only if they are also printed on the product label.

EC REP
Emergo Europe
Molenstraat 15
2513 BH The Hague
Netherlands

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

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Biocompatibility

(b)(4)

[redacted]

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

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Materials

The materials used to manufacture the implants in the Renovis S128 ALIF System all conform to ASTM F standards. All materials have a long history of usage for surgical implants. Table 1 lists all of the materials used to manufacture the implants along with the applicable ASTM standards.

Table 1

Family	Material	ASTM Standard
(b)(4) [redacted]		

Cleaning Process

(b)(4) [redacted]

Biocompatibility Statement

(b)(4) [redacted]

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

(b)(4) Third Party Information

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Reprocessing, Sterilization and Shelf Life

(b)(4)

[redacted]

Shelf life

NA – This device is not provided sterile and storage conditions should not affect device safety or effectiveness. The shelf life of a facility sterilized component should be determined by that facility per their internal SOPs.

Packaging

(b)(4)

[redacted]

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

(b)(4) Standard Operating Procedures

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Appendix A: Complete Listing of Instruments

Table A-1: Instrument Listing

Part Number	Description
2128-001-001	Implant Inserter
2128-001-002	Distractor Implant Inserter Assembly
2128-001-003	Implant Impactor
2128-001-004	Cover Plate Inserter Assembly
2128-001-005	Trial Implant/Bullet Distractor Inserter
2128-001-006	Rasp
2128-001-007	Adjustable Drill Guide
2128-001-008	Captured Spring Loaded Awl
2128-001-009	Cover Plate Driver
2128-001-010	Screw Driver with Universal Joint
2128-001-011	Screw Driver with Solid Shaft
2128-001-012	Awl with Universal Joint
2128-001-013	Modular Drill Bit 3.0mm Diameter 8mm Engagement Length
2128-001-014	Modular Flexible Drill Shaft
2128-001-015	Small Cup Curette
2128-001-016	Large Cup Curette
2128-001-017	Small Up Angled Cup Curette
2128-001-018	Ringed Curette
2128-001-019	Chisel
2128-001-020	23mm Sharp Cobb
2128-001-021	17mm Sharp Cobb
2128-001-022	Large Up Angled Cup Curette
2128-001-023	5mm Sypert Rongeur
2128-001-024	10mm Sypert Rongeur
2128-001-025	4mm Pituitary Rongeur
2128-001-026	8mm Pituitary Rongeur
2128-001-027	3mm Kerrison Rongeur
2128-001-028	6mm Kerrison Rongeur
2001-000-003	Reverse Large Axial Ratcheting Driver Handle
2128-001-030	Large Modular Handle
2128-001-031	Large Threaded Handle
2128-001-032	Angled Implant Inserter
2128-001-033	Angled Cover Plate Inserter
2128-001-034	Modular Screw Driver Bit
2128-001-035	Packing Block
2128-001-036	Long Scalpel Handle
2128-003-026	Small Paddle Sizer
2128-003-428	Medium Paddle Sizer
2128-003-830	Large Paddle Sizer
2128-002-009	9mm Bullet Nose Distractor
2128-002-011/021	11mm-21mm Bullet Nose Distractors
2128-302-611/621	11mm-21mm Trials, 30 X 26, 7° Lordosis
2128-342-811/821	11mm-21mm Trials, 34 X 28, 7° Lordosis
2128-383-011/021	11mm-21mm Trials, 38 X 30, 7° Lordosis
2129-302-611/621	11mm-21mm Trial, 30 X 26, 12° Lordosis
2129-342-811/821	11mm-21mm Trial, 34 X 28, 12° Lordosis
2129-383-011/021	11mm-21mm Trials, 38 X 30, 12° Lordosis

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

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Attachment 1: (b)(4) [redacted]

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Attachment 2: (b)(4) [redacted] Report

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Performance Bench Testing

Mechanical testing – standard

(b)(4) [redacted]

The worst case construct underwent the following testing:

- Static Compression Testing per ASTM F2077
- Dynamic Compression Testing per ASTM F2077
- Static Shear Compression Testing per ASTM F2077
- Dynamic Shear Compression Testing per ASTM F2077
- Expulsion Testing w/screws per ASTM Draft Standard F04.25.02.02
- Expulsion Testing w/o screws per ASTM Draft Standard F04.25.02.02
- Subsidence Testing per ASTM F2267

The final report(s) is included as Attachment 022.

Sample coupons of the Titanium porous structure have undergone the following testing:

- Shear testing of metallic coatings per ASTM F1044
- Tensile testing of metallic coatings per ASTM F1147
- Abrasion per ASTM F1978
- Porosity and microstructure per ASTM F1854

The final report(s) is included as Attachment 023.

(b)(4) [redacted]

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

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COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Katherine Kavlock

Subject: 510(k) Number K131122

To: The Record

Please list CTS decision code: SE - Substantially Equivalent

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

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

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

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

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

Branch Chief Sign-Off	Anton E. Dmitriev 2013.09.18 12:47:25 -04'00'
Division Sign-Off	Ronald P. Jean -S 2013.09.18 14:15:30 -04'00'

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K131122/S001

FDA CDRH DMC
AUG 19 2013
Received

MEDICEPT
Medical Device Compliance Consulting

August 16, 2013

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

Re: K131122/S001 – Response to Additional Information Request - Abbreviated 510(k)
Renovis S128 ALIF System

Dear Ms. Kavlock:

Enclosed please find our response to the Additional Information request received by email on 6/19/2013. In addition, the responses include the text from the email communication received from you on 7/9/2013, which was in response to our Request for Clarification.

(b)(4)

[redacted]

"Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff", December 31, 2012.

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

Records processed under FOIA Request # 2015-8696; Released by CDRH on 03-15-2016

If there are any questions regarding this submission, please contact me at 401-330-8264 or by email at sorton@medicept.com.

Sincerely yours,

Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Inc.
for
Renovis Surgical Technologies

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

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MEDICEPT
Medical Device Compliance Consulting

August 16, 2013

Katherine Kavlock
U.S. Food and Drug Administration
Center for Devices and Radiological Health/ODE/DOD/ASDB
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Sincerely yours,

Sharyn Orton, Ph.D.
Senior Consultant
MEDIcept, Inc.
for
Renovis Surgical Technologies

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

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TABLE OF FILES

Document name	File number
Cover letter K131122 S001	(b)(4) [redacted]
K131122 S001 Deficiency	(b)(4) [redacted]
K131122 S001 Deficiency	[redacted]
K131122 S001 Deficiency	[redacted]
K131122 S001 Deficiency	[redacted]
K131122 S001 Deficiency	[redacted]
K131122 S001 Deficiency	[redacted]
K131122 S001 Deficiency	[redacted]
K131122 S001 Deficiency	[redacted]
K131122 S001 Deficiency	[redacted]
K131122 corrected	(b)(4) [redacted]

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

(b)(4) Deficiencies

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(b)(4) Manufacturing Information

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(b)(4) Manufacturing Information

[redacted]

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ATTACHMENT D

Li X, Feng Y-F, Wang C-T, Li G-C, Lei W, et al. (2012) Evaluation of Biological Properties of Electron Beam Melted Ti6Al4V Implant with Biomimetic Coating In Vitro and In Vivo. PLoS ONE 7(12): e52049. doi:10.1371/journal.pone.0052049

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Evaluation of Biological Properties of Electron Beam Melted Ti6Al4V Implant with Biomimetic Coating In Vitro and In Vivo

Xiang Li[1], Ya-Fei Feng[2], Cheng-Tao Wang[1], Guo-Chen Li[3], Wei Lei[2], Zhi-Yong Zhang[2,4]*, Lin Wang[2]*

1 School of Mechanical Engineering, Shanghai Jiao Tong University, State Key Laboratory of Mechanical System and Vibration, Shanghai, China, **2** Department of Orthopaedics, Xijing Hospital, The Fourth Military Medical University, Xi'an, China, **3** Department of Orthopaedics, Tangdu Hospital, The Fourth Military Medical University, Xi'an China, **4** Department of Plastic and Reconstructive Surgery, Shanghai 9th People's Hospital, Shanghai Key Laboratory of Tissue Engineering, School of Medicine, Shanghai Jiao Tong University, Shanghai, China

Abstract

Background: High strength porous titanium implants are widely used for the reconstruction of craniofacial defects because of their similar mechanical properties to those of bone. The recent introduction of electron beam melting (EBM) technique allows a direct digitally enabled fabrication of patient specific porous titanium implants, whereas both their in vitro and in vivo biological performance need further investigation.

Methods: In the present study, we fabricated porous Ti6Al4V implants with controlled porous structure by EBM process, analyzed their mechanical properties, and conducted the surface modification with biomimetic approach. The bioactivities of EBM porous titanium in vitro and in vivo were evaluated between implants with and without biomimetic apatite coating.

Results: The physical property of the porous implants, containing the compressive strength being 163 - 286 MPa and the Young's modulus being 14.5–38.5 GPa, is similar to cortical bone. The in vitro culture of osteoblasts on the porous Ti6Al4V implants has shown a favorable circumstance for cell attachment and proliferation as well as cell morphology and spreading, which were comparable with the implants coating with bone-like apatite. In vivo, histological analysis has obtained a rapid ingrowth of bone tissue from calvarial margins toward the center of bone defect in 12 weeks. We observed similar increasing rate of bone ingrowth and percentage of bone formation within coated and uncoated implants, all of which achieved a successful bridging of the defect in 12 weeks after the implantation.

Conclusions: This study demonstrated that the EBM porous Ti6Al4V implant not only reduced the stress-shielding but also exerted appropriate osteoconductive properties, as well as the apatite coated group. The results opened up the possibility of using purely porous titanium alloy scaffolds to reconstruct specific bone defects in the maxillofacial and orthopedic fields.

Citation: Li X, Feng Y F, Wang C T, Li G C, Lei W, et al. (2012) Evaluation of Biological Properties of Electron Beam Melted Ti6Al4V Implant with Biomimetic Coating In Vitro and In Vivo. PLoS ONE 7(12): e52049. doi:10.1371/journal.pone.0052049

Editor: Jie Zheng, University of Akron, United States of America

Received September 16, 2012; **Accepted** November 8, 2012; **Published** December 18, 2012

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Funding: The authors would like to thank Contract Grant Sponsor: XIJING ZHUTUI Foundation (XJZT10M07), the Project supported by National Key Technology R&D Program (2012BAI18B07), the Ph.D. Programs Foundation of the Ministry of Education of China (Grant No. 20100073120051) and the Research Project of State Key Laboratory of Mechanical System and Vibration (Grant No. MSV201114) for their support to this work. The funders played no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: The authors have declared that no competing interests exist.

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These authors contribute equally to this work.

Introduction

Titanium and titanium alloys have been widely used in orthopedic and dental implants due to low density, excellent mechanical properties, favorable biocompatibility, and good corrosion resistance. However, clinical practices and studies have shown that the mechanical mismatch between metallic implant and natural bone may lead to stress shielding, and thus cause bone resorption and eventually the failure of metallic implant fixation [1]. Porous metallic structure can be utilized to overcome this drawback, which not only reduced the mechanical mismatch but also achieved stable long term fixation by promoting full bone ingrowth [2,3]. Many techniques have been investigated to produce porous metallic structure, including powder sintering approach, space holder method, combustion synthesis, plasma spraying, and polymeric sponge replication [3 6]. However, these conventional techniques have very limited control of the internal pore architecture and the external shape of the porous titanium implants, which hinder further application of porous titanium.

Rapid prototyping (RP), generally known as solid freeform fabrication (SFF), is a type of technologies that can automatically construct physical models from computer aided design (CAD) data. The applications of state of the art RP techniques for fabricating polymeric tissue engineering (TE) scaffolds were reviewed by Leong and Hutmacher [7,8], with detailed illustration to show the superiority of RP techniques over the conventional

2-23
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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fabrication methods. Direct fabrication of metallic components for biomedical application with RP approaches, such as three dimensional fiber deposition [9], laser engineered net shaping [10], direct laser forming [11] and so on, has been shown to become a feasible and promising manufacturing technology in producing porous Ti6Al4V scaffolds with interconnected porous networks. Recently, selective electron beam melting (EBM) approach as a metal rapid prototyping process has been studied for fabricating patient specific porous orthopedic implants [12]. The EBM porous titanium implant not only avoided the stress shielding effects in vivo for similar mechanical properties with native bone [13], but also matched irregular defect at specific site such as skull, maxillofacial and bone joint region [Fig. 1]. Heinl et al. has reported that cellular Ti6Al4V structures with inter connected macro porosity fabricated by EBM might have favorable long term stability and were suitable for orthopedic applications [14].

In addition to the internal structure and external shape, the implant surface physicochemical properties are also critical for bone implant integration. As solid titanium and alloys are generally encapsulated by fibrous tissue after implantation for their bioinert nature [15,16], many surface modification methods, including plasma spraying [17], sol gel [18], electrophoretic deposition [19], sputter deposition [20] and micro arc oxidation [21], were applied to improve the bone implant integration of this kind of implants. The biomimetic approach, which via soaking implants in simulated body fluids (SBF) at a physiological temperature and pH, has been shown to be a superior option due to its low operation temperature and homogenously bone like carbonated apatite deposition [22 24]. Barrere et al. [25] reported that the biomimetic coating enhanced the implant bone in tegration and were beneficial for the long term fixation of metal prostheses in the load bearing applications. However, few studies have analyzed the biological performance of EBM porous titanium implants with biomimetic coating.

The aim of this study was to fabricate Ti6Al4V implants with well controlled porous structure using EBM process, and to evaluate the bioactivity of this porous implant with or without biomimetic apatite coating in vivo and in vitro. The implant physical properties were examined by scanning electron micros copy, micro computer tomography, and digital microscope. The implant surfaces were modified by biomimetic approach and characterized by energy dispersive X ray analysis, X ray diffrac tion and Fourier transform infrared spectroscopy. In vitro, experiments were performed to assess cell attachment, viability, cell proliferation and differentiation. In vivo, samples were implanted into 12 mm bone defects in calvaria of rabbits, and bone ingrowth and bone implant bonding was evaluated by histology and histomorphometry.

Materials and Methods

Preparation of Porous Ti6Al4V Implant

Porous Ti6Al4V implant was fabricated using electron beam melting process as previously described [12]. Briefly, the external shape and internal porous structures were designed with commercial CAD software (Unigraphics NX, EDS). The CAD data of the structures was converted into STL data which then imported into Materialise's Magics software, and converted into input file for EBM. The samples were produced on an Arcam's EBM machine (EBM S12, Arcam AB, Sweden).

Characterization of Porous Ti6Al4V Implant

The porous structures of the EBM produced samples were observed using a scanning electron microscope (SEM, JSM 6460, JEOL, Japan) equipped with an energy dispersive X ray analyzer (EDX, Oxford, UK). The structural analysis using micro computer tomography (μCT, Locus SP, GE, USA) was conducted prior to the chemical treatments to determine the mean pore size and the porosity of the implants. The resolution was 20 μm. The three dimensional (3D) surface topography of the samples was examined by optical profiler (OP, Wyko NT9300, Veeco, USA). Five samples were measured from each of the two different surfaces (top&bottom and lateral) to obtain an average roughness value R_a. The porosity of EBM produced samples was evaluated from the weight and the apparent volume of the specimen (n 5). Compression tests were conducted to determine the mechanical properties of the EBM Ti6Al4V implants (n 5) using a material

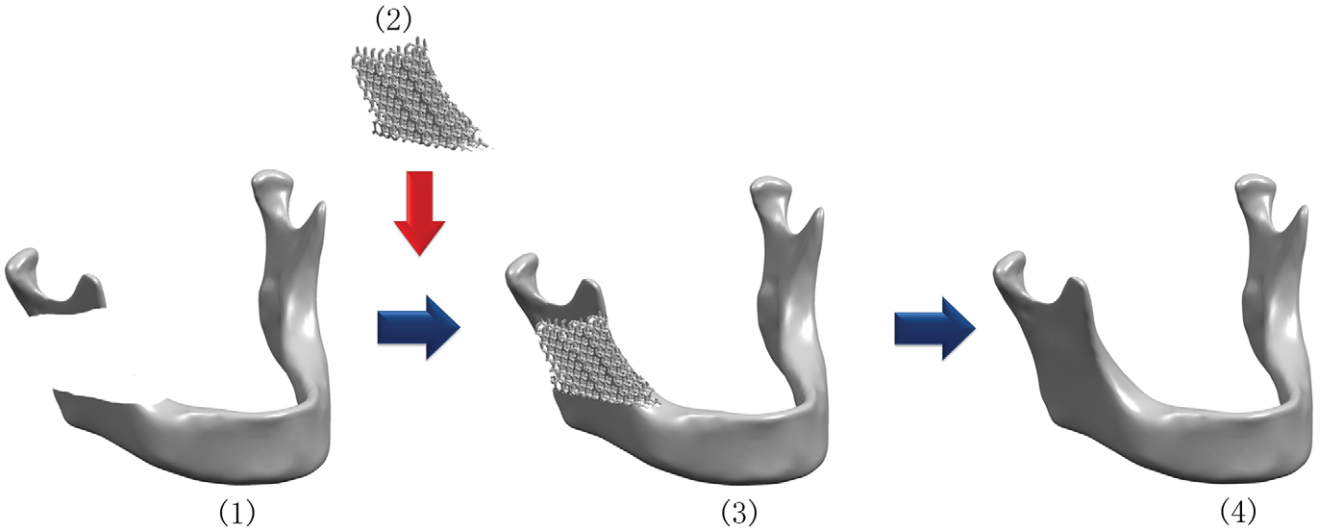

Figure 1. The flow diagram showed the design of electron beam melting (EBM) porous Ti6Al4V implant with CAD for repair of mandibular bone defect: (**1**) acquisition of the CT data of the patients; (**2**) design with CAD and fabrication of custom EBM porous titanium implant; (**3**) implantation of the patient specific porous implant; (**4**) reconstruction of the bone defect.
doi:10.1371/journal.pone.0052049.g001

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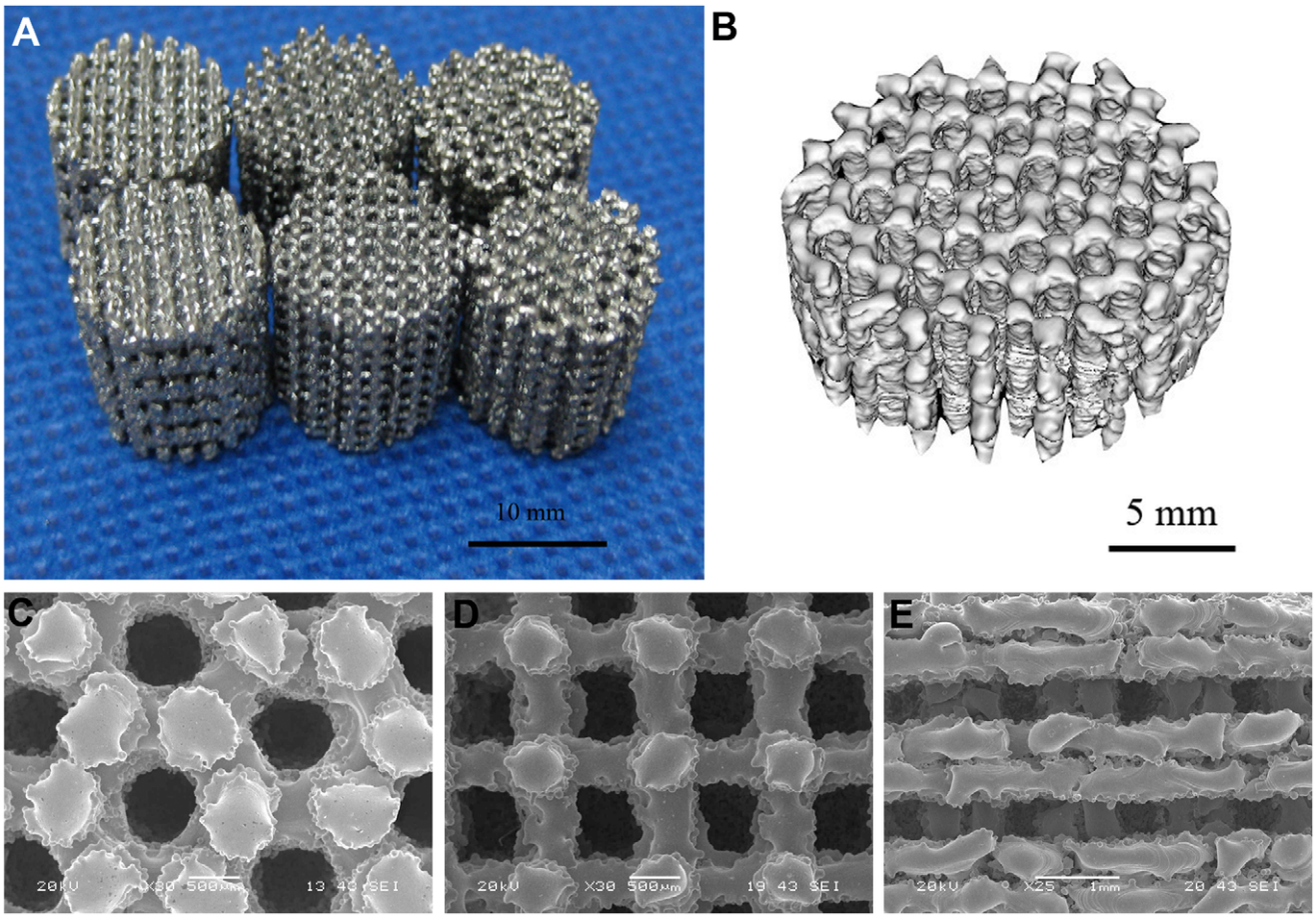

Figure 2. Characterization of porous Ti6Al4V samples. (**A**) Porous Ti6Al4V implants fabricated by electron beam melting process. (**B**) Reconstructed 3D micro CT image of the porous implant with honey like structure. SEM images of porous Ti6Al4V samples with (**C**) honeycomb like structure, (**D**) orthogonal structure, (**E**) layer structure.
doi:10.1371/journal.pone.0052049.g002

testing system (MTS 810) with a 10 kN load cell at room temperature. The cross head speed was set at 0.5 mm/min. The elastic modulus E was calculated from the slope of the compressive stress strain curve in the linear elastic region. The compressive yield strength $\sigma_{0.2}$ was determined from the stress strain curve according to the 0.2% offset method, while the maximum strength σ_{max} was calculated by dividing the highest load by the initial cross sectional area.

Biomimetic Coating

Samples for surface modification were machined to cylinder shape with diameter in 11.6 mm and height in 5 mm. Before chemical treatment, samples were washed with isopropanol and distilled water in an ultrasonic cleaner, and then dried in air. Alkali treatment was performed by soaking these samples in 10 *M* NaOH aqueous solution at 60°C for 24h, then washed gently with distilled water. The alkali treated samples were heated to 600°C (at a rate of 5°C min^{-1}) in an electric furnace, kept at 600°C for 1h, and then allowed to cool to room temperature in the furnace [23]. The alkali heat treated samples were immersed in SBF solution under static conditions at 37°C for 14 days. The solution was changed every 2 days to maintain the solution concentrations. The SBF solution was prepared according to Kokubo et al's method [26]. Briefly, reagent grade chemicals of NaC1, $NaHCO_3$, KCl, $K_2HOP_3 \cdot 3H_2O$, $MgC1_2 \cdot 6H_2O$, $CaC1_2$, and Na_2SO_4 were dissolved into distilled water, and buffered at pH 7.40 with hydrochloric acid and tris hydroxymethyl aminomethane at 36.5±1.5°C.

Characterization of Implant Surface with Biomimetic Coating

After immersion in SBF for 14 days, the specimens were rinsed in distilled water and dried in vacuum desiccator. Surface morphologies of the samples after chemical treatment and soaking in SBF were examined by scanning electron microscope. The thin film X ray diffraction (TF XRD) measurement was performed on a Rigaku X ray diffractometer (Cu Kα radiation, 40 kV, 30 mA). The data was collected in the 2θ ranges of 20 60° with a step size of 0.02°. FTIR spectra were measured in transmission using the KBr technique in the range from 4000 to 400 cm^{-1} at a resolution of 4 cm^{-1}. Approximately 1 mg of the coatings formed on the chemically treated titanium sample after soaking in SBF solutions for 14 days was removed from the substrate, then mixed with 500 mg of dry KBr powder and ground using an agate mortar and pestle. The resulting mixture was pressed into transparent pellets with diameter of 13 mm and applying force of 10^5 N [27]. Both the EBM Ti6Al4V implants (TiI) and biomimetic apatite coated implants (TiC) were used for in vitro and in vivo analysis in the present study.

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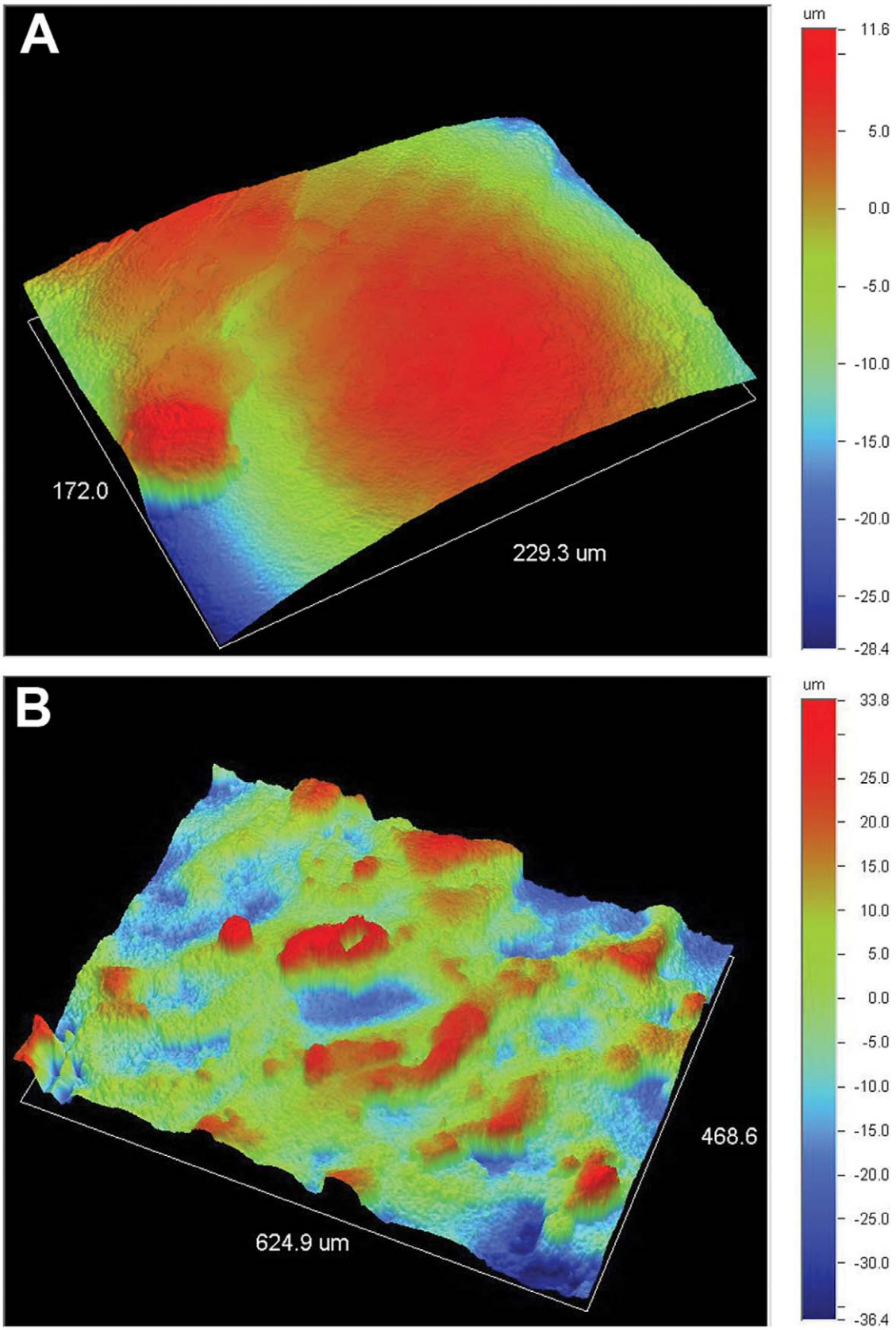

Figure 3. Digital topographic images of the sample surface. The images exhibited a rough anisotropic surface with the roughness R_a values of the (**A**) top and (**B**) lateral surfaces being in the range of 5 10 and 15 21 µm.
doi:10.1371/journal.pone.0052049.g003

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Table 1. Geometric characteristics and mechanical properties of porous titanium samples.

	Honey-like structure	Orthogonal structure	Layering structure	Cortical bone
Porosity (%)	51.4±2.4	61.2±3.7	55.3±2.6	
Pore size (μm)	~600	~600	~500	
Strut size (μm)	~650	~500	~900	
E (GPa)	25.9±2.8	14.5±3.1	38.5±6.7	10 30
$\sigma_{0.2}$ (MPa)	185.4±15.9	138.2±8.6	194.4±12.1	~138
σ_{max} (MPa)	286.6±35.5	163.8±11.3	235.6±18.3	~193

E, the elastic modulus.
$\sigma_{0.2}$, the compressive yield strength.
σ_{max}, the compressive maximum strength.
doi:10.1371/journal.pone.0052049.t001

Cell Seeding and Co-culture with Implant

All samples were sterilized in ethylene oxide gas before cell seeding. Osteoblastic cells were isolated from new born New Zealand rabbit's calvaria [28]. Cells were cultured in DMEM supplemented with 10% BCS and 1% penicillin/streptomycin and incubated at 37°C in a 5% CO_2, 100% relative humidity incubator. The third passage cells were used in the present study. Osteoblasts were seeded on the scaffolds at a density of 6×10^5 cells/ml.

Cell Attachment and Morphology

Samples were removed from culture and washed with phosphate buffered saline after 14 days incubation, and then fixed in 2% v/v glutaraldehyde in 0.1 M sodium cacodylate buffer at 4°C overnight for attachment and morphological observation. The samples were washed in the buffer, dehydrated through an ethanol series, critical point dried, lastly sputtered with gold, and were analyzed using a scanning electron microscope (SEM) operating at 15 kV and a semiautomatic interactive image analyzer.

Histological Examination in vitro

Samples for histological study were fixed in 10% formalin for 7 days, dehydrated through an ethanol series, cleared with toluene, and embedded in methylmethacrylate. After polymerization, thin sections were prepared with a modified sawing microtome technique. The sections were stained with Haematoxylin and Eosin (H&E) and examined with a standard microscope (Leica, Wetzlar, Germany).

Cell Proliferation

Cell proliferation was assessed using a methylthiazol tetrazolium (MTT) assay. Briefly, 800 μl serum free medium and 80 μl MTT solution were added to each sample. After 4 h of incubation at 37°C in a fully humidified atmosphere with 5% CO_2 in air, MTT was taken up by active cells and reduced in the mitochondria to insoluble purple formazan granules. Subsequently, the medium was discarded, and the precipitated formazan was then dissolved in dimethyl sulfoxide (DMSO). After 10 min of slow shaking, the absorbance was read at 570 nm using a Bio Rad 500 spectrophotometric microplate reader.

Implantation Assay

All animal experiments were performed in accordance with the National Institutes of Health Guidelines for the Use of Laboratory Animals. The animals used in the current study were obtained from protocols approved by the Fourth Military Medical University Committee on Animal Care (Permit Number: 12090). Thirty male New Zealand white rabbits, weighing 2.5 3.0 kg, were used to examine the implant bone integration and bone ingrowth of the EBM Ti6Al4V porous implants of orthogonal structure with or without biomimetic apatite coating in experimental cranial implantation. All animals were anaesthetized by intramuscular injection of Ketamine. Two 12 mm full thickness calvaria defects were drilled. The implants were placed alternately in the right or left defect. The breath and heart rate of rabbits were carefully monitored to ensure that they were under anesthetic and painless before recovering from anesthesia. Each rabbit was administered 400,000 U of penicillin intraoperatively and on the first postoperative day to prevent infection. The animals were

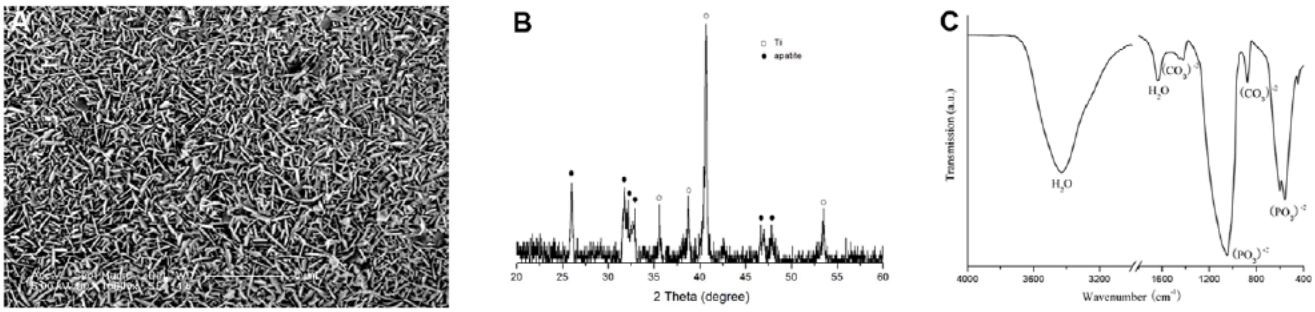

Figure 4. Characterization of porous titanium with biomimetic coating. (**A**) SEM image of the precipitate on sample surfaces soaked in SBF for 14 days. (**B**). TF XRD pattern of the sample surface after alkali heat treatment and subsequently immersion in SBF for 14 days. (**C**) FTIR spectra of chemically pretreated Ti6Al4V samples soaked in SBF for 14 days.
doi:10.1371/journal.pone.0052049.g004

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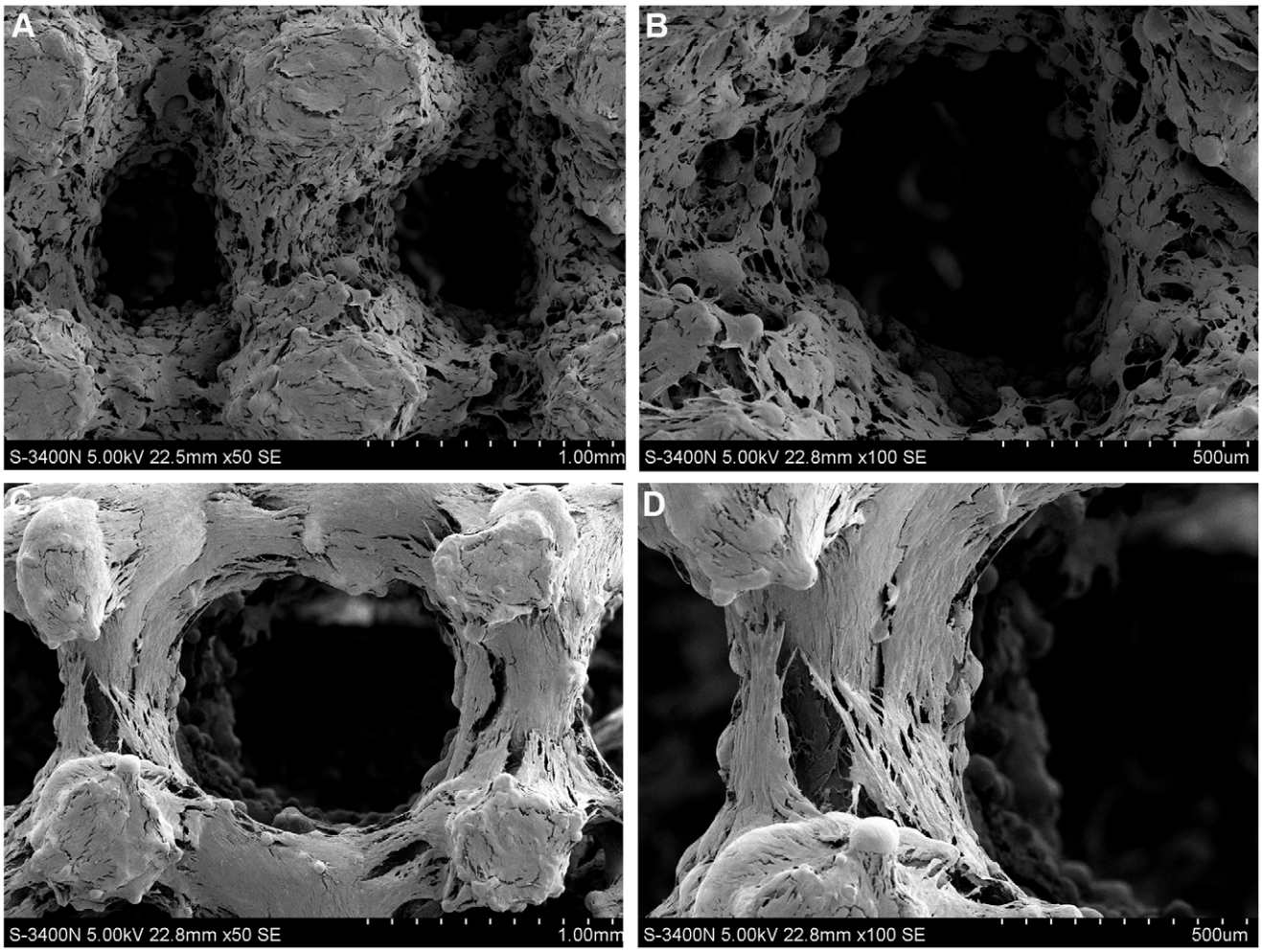

Figure 5. SEM morphologies of cells on porous titanium samples after 14 days of culture. A great number of osteoblasts attached to the (**A B**) pure porous titanium scaffolds and (**C D**) porous titanium scaffolds with biomimetic coating, and presented an elongated morphology with cytoplasmic extensions on scaffolds. There were no obvious differences in cell adhesion and morphology between the uncoated and coated samples.
doi:10.1371/journal.pone.0052049.g005

anaesthetized and sacrificed by intra cardiac overdose of sodium pentobarbital at 4, 8 and 12 weeks after implantation.

Fluorochrome Labeling

Sequential fluorochrome markers were administered after implantation. Tetracycline (30 mg/kg, Sigma, USA) was administered 2 weeks and Calcein Green (8 mg/kg, Sigma, USA) was administered 3 days before the animals were sacrificed using intramuscular injection. After the animals were sacrificed at 12 weeks post surgery, the implants were retrieved for fluorescence analysis.

Histological and Histomorphometric Analysis

All retrieved specimens were fixed in 10% formalin for 7 days. After fixation, the samples were dehydrated in a graded series of ethanol and embedded in methylmethacrylate. After polymerization, thin sections were prepared with a modified sawing microtome technique and stained with 1.2% trinitrophenol and 1% acid fuchsin (Von Gieson staining). The qualitative analysis of bone formation and fluorochrome markers were performed using a light/fluorescence microscope (Leica LA Microsystems, Bensheim, Germany). Image analysis was performed using the Image Pro Plus software (version 6.0, Media Cybernetics, USA). The amount of newly formed bone inside the defect was evaluated and expressed as percentage of bone area in total available pore space [(bone area/(total implant area total scaffold area)×100%]. In addition, the bone mineralization apposition rate (MAR, vertical spacing between two fluorochrome markers/injection interval) was analyzed by from the images of fluorochrome labeling, which generally indicated the new bone growth rate.

Statistical Analysis

All the values in the experiment were expressed as the mean ± standard deviation, and were compared using one way analysis of variance (ANOVA). Differences at $p<0.05$ were considered statistically significant.

Results

Structural Characterization

The Ti6Al4V samples produced by EBM process were shown in Fig. 2A. The pore architectures of samples were examined using micro CT and SEM. The reconstructed 3D images from micro CT measurements and micrographs from SEM examination were

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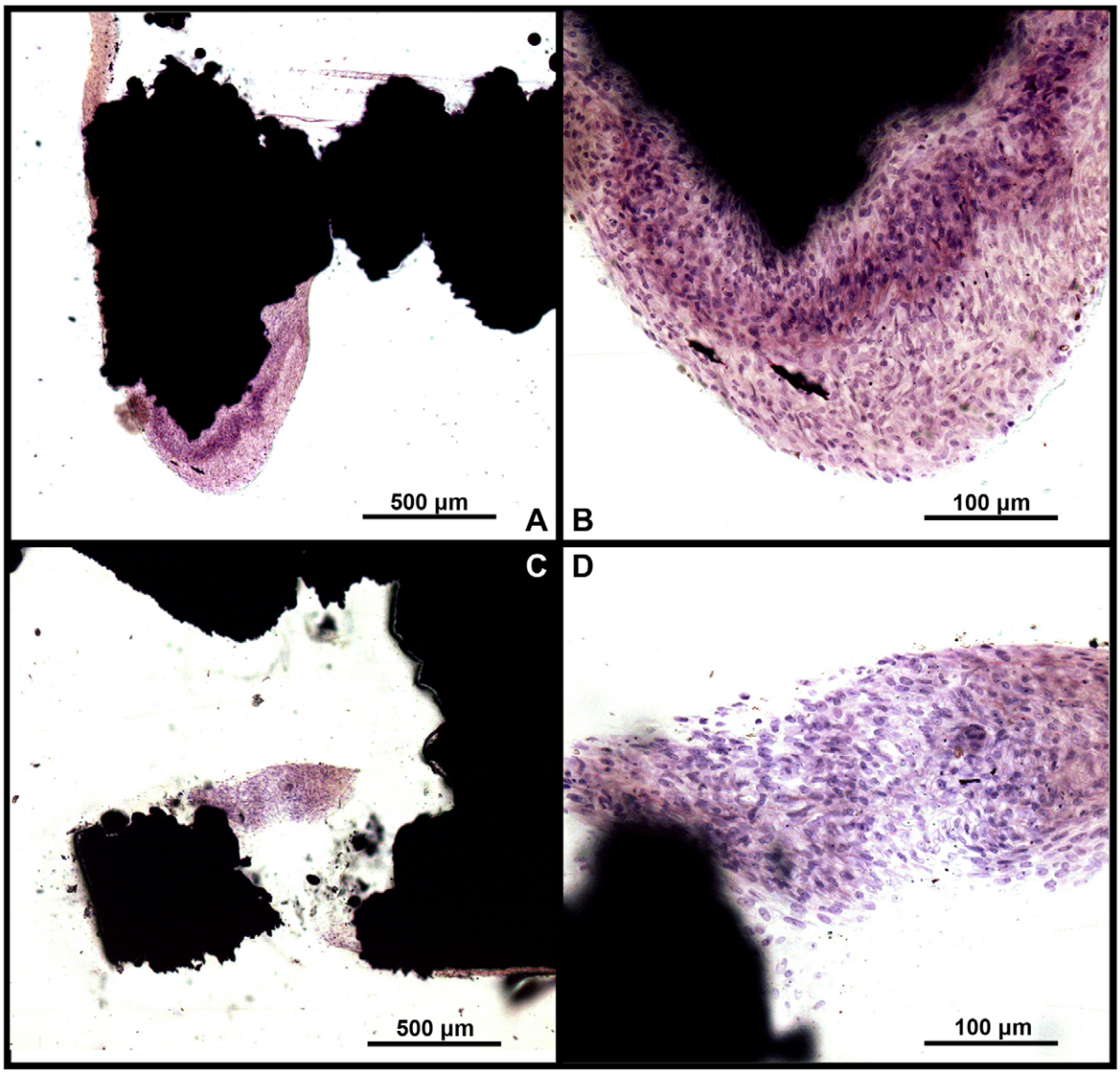

Figure 6. H&E stained sections of sample after 14 days of in vitro culture. Large amount of extracellular matrix deposited among the cells, and some cells migrated into the inner pore of both (**A B**) uncoated and (**C D**) coated samples.
doi:10.1371/journal.pone.0052049.g006

shown in Fig. 2B and Fig. 2C E, respectively. All samples exhibited fully interconnected porous networks. This is one of the most important requirements for tissue ingrowth. Some molten particles could be found in the pores. The three dimensional topographies of the implants surfaces, illustrated in Fig. 3, exhibited a rough anisotropic surface. The roughness R_a values of the top and lateral surfaces were in the range of 5 10 and 15 21 µm. The sample lateral surfaces were rougher compared to the top surfaces due to adherent molten powder particles. For porous implants with different internal structure, the geometric char acteristics and mechanical properties of the samples were shown in Table 1. The orthogonal structure implants, which exerted better mechanical properties than two other kinds of implants, were used for the in vitro and vivo analysis.

Surface Modification

In Figure 4A, the SEM photographs showed a homogeneous surface layer formed on the surface of implants. EDX analysis revealed calcium, magnesium, sodium and phosphorus to be presented in the surface. The detected Ca/P molar ratio was 1.65. The TF XRD pattern of the sample surfaces after alkali heat treatment and subsequent immersion in SBF for 14 days was shown in Fig. 4B. The TF XRD pattern exhibited broad diffraction lines. The position of these diffraction lines indicated that the deposits are formed of poor crystalline hydroxyapatite. The phase composition of the layer was analyzed in detail using FTIR (Fig. 4C). The spectra showed featureless phosphate and carbonate bands. Intense and broad bands were assigned to oxygen hydrogen groups, and stretching and bonding were observed at 3435 and 1642 cm^{1} respectively. A broad band at about 1420 1450 cm^{1} from the carbonate groups was in corporated in the apatite structure. These carbonate groups gave rise to the band at 875 cm^{1}. A broad band in the range of 960 to 1200 cm^{1} from v_3 P O antisymmetric stretching vibration, indicated the deviation of phosphate ions from the ideal tetrahedral structure. The bending modes of the O P O bonds

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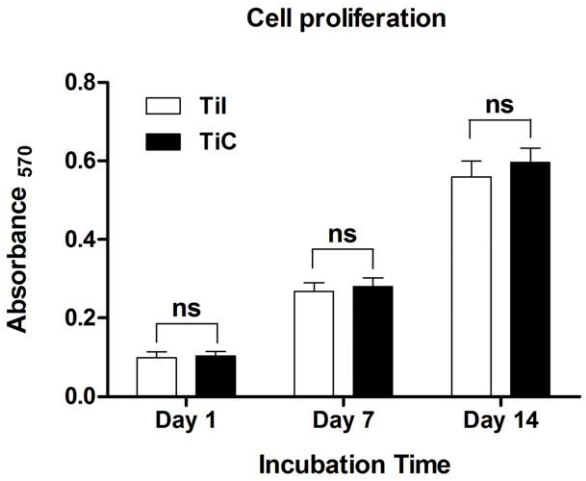

Figure 7. Cell viability of the sample over 14 days of in vitro culture. The cells on the porous titanium exerted a high and sustained proliferation rate within 14 days, and no significant difference was observed between the uncoated and coated samples at each timepoint ($P>0.05$). Til, pure porous titanium implant; TiC, porous titanium implant with biomimetic coating.
doi:10.1371/journal.pone.0052049.g007

in the phosphates were found in the spectral range from 560 to 602 cm ^{1}. HPO_4^{2} groups were detected at 1108 cm ^{1} (v_3 mode). Therefore, the precipitate formed in SBF was characterized in a poorly crystallized or amorphous carbonated Ca P phase.

Cell Attachment and Morphology

After 14 days of culture, it was found that cells adhered to the modified surface, spread out and proliferated into the multilayer structures. The osteoblasts achieved confluence and cover the Ti surface completely with large amount of extracellular matrix (ECM) deposited among the cells, as demonstrated on the SEM images (Fig. 5) and H&E stained section (Fig. 6) of the cell/implant constructs. In addition, some cells have migrated into the inner of porous implants, but they did not span across the total implant. The cross section histological staining showed a decrease of cell number from top to bottom of porous implants. Moreover, there was no obviously difference in morphology and dense of cells between porous implants with and without biomimetic coating.

Cell Proliferation

MTT assay was used to study the cellular viability and proliferation of the cell culture in the biomimetically modified samples. It showed the maintenance of high cellular viability and a rapid proliferation of cells within 14 days (Fig. 7). The cell viability on EBM porous implant was similar to that on the biomimetic apatite coated implants at each timepoint (all $P>0.05$).

Fluorochrome Labeling

Bone remodeling was validated by interrupted fluorescent bone labeling and new bone deposition. The labeling was detected in the regenerated bone in the pores of EBM porous implants, revealing that the increase rate of bone deposition progressed into the pores of the scaffolds (Fig. 8A D). The fluorescent labeling indicated similar bone ingrowth from the bone implants interface to the center of the defect in pure porous implants compared with biomimetic apatite coated porous implants, as well as the fluorescent labeling analysis showed that there were no differences in MAR between the coated (2.22 ± 0.25 μm/d) and uncoated implants (2.18 ± 0.27 μm/d, $P>0.05$) (Fig. 8E), indicating similar rate of bone ingrowth within the porous titanium with and without biomimetic apatite coating.

Histological and Histomorphometric Analysis

To evaluate the tissue response to the implanted scaffolds and the defect healing progress, we performed histological analysis on the tissue/implants interface and the internal area of the implants. For all Ti6Al4V implants, no foreign body or inflammatory reaction was observed. Bone formation was found to start from the host bone bed towards the implant in all implants. Four weeks after surgery, histological observations revealed that a small amount of new immature bone tissue grew from the rim of bone defect and began to integrate with the periphery of porous implants, with the direct deposition of newly formed bone onto the surface of implants (Fig. 9A B, bone tissue in red color while Ti6Al4V implant in black color). After 8 weeks of implantation, histological evaluation indicated progressive growth of more newly formed bone from the calvarial margins toward the center of the bone defect. The newly formed bone integrated well with implant surface (Fig. 9C D). At 12 weeks, the newly formed bone has successfully bridged the calvarial defect, and the majority of the pores at the bottom part of the implants were filled with bone tissue, which were directly bridged with the calvarial defects (indicated in red color Fig. 9E F). In addition, the process of bone remodeling was spotted in all the implant sites. Quantitative histomorphometric analysis demonstrated a rapid and continuous new bone formation in the defect region in both coated and uncoated implants at each timepoint during the whole experiment (all $P>0.05$) (Fig. 10).

Discussion

The EBM process is a new additive manufacturing technique with great capability to fabricate dense and porous Ti6Al4V implants with better control on the both internal structure and external shape [29,30,31,32]. In addition, the EBM production process is much faster comparing with conventional manufacturing methods using laser beam. In EBM process, the high power electron beam is used instead of conventional laser beam. With regards to energy utilization efficiency (EUE) during metal sintering, high power electron beam can be as high as 95 percent, which is 5 to 10 times higher than the EUE of the laser beam; whereas laser beam may lose up to 95% of its energy, due to the light reflection by the metal powder during the sintering. This leads to 3 to 5 times faster processing speed of EBM than other laser beam based metal additive fabrication methods. Furthermore, thanks to the high EUE of electron beam, EBM process provides a better and more reliable fabrication process compared to selective laser sintering (SLS), by fully melting the metal particles to manufacture high quality of implants, which is completely void free. The whole EBM process occurs in an ultra high vacuum environment, eliminating any imperfections caused by oxidation.

The Young's modulus of solid Ti6Al4V implants produced by Arcam EBM is up to 120 GPa [32]. In comparison with the solid ones, the Young's modulus of porous Ti6Al4V implants in current study is similar to cortical bone, which could minimize stress shielding. It is obvious that the porous structures help to reduce the mechanical mismatches between metallic implants and host bone tissue. The ideal porous implants should provide a good mechanical environment for initial function and appropriate remodeling of regenerating tissue while concurrently providing sufficient porosity for cell migration and tissue ingrowth. Whereas, these

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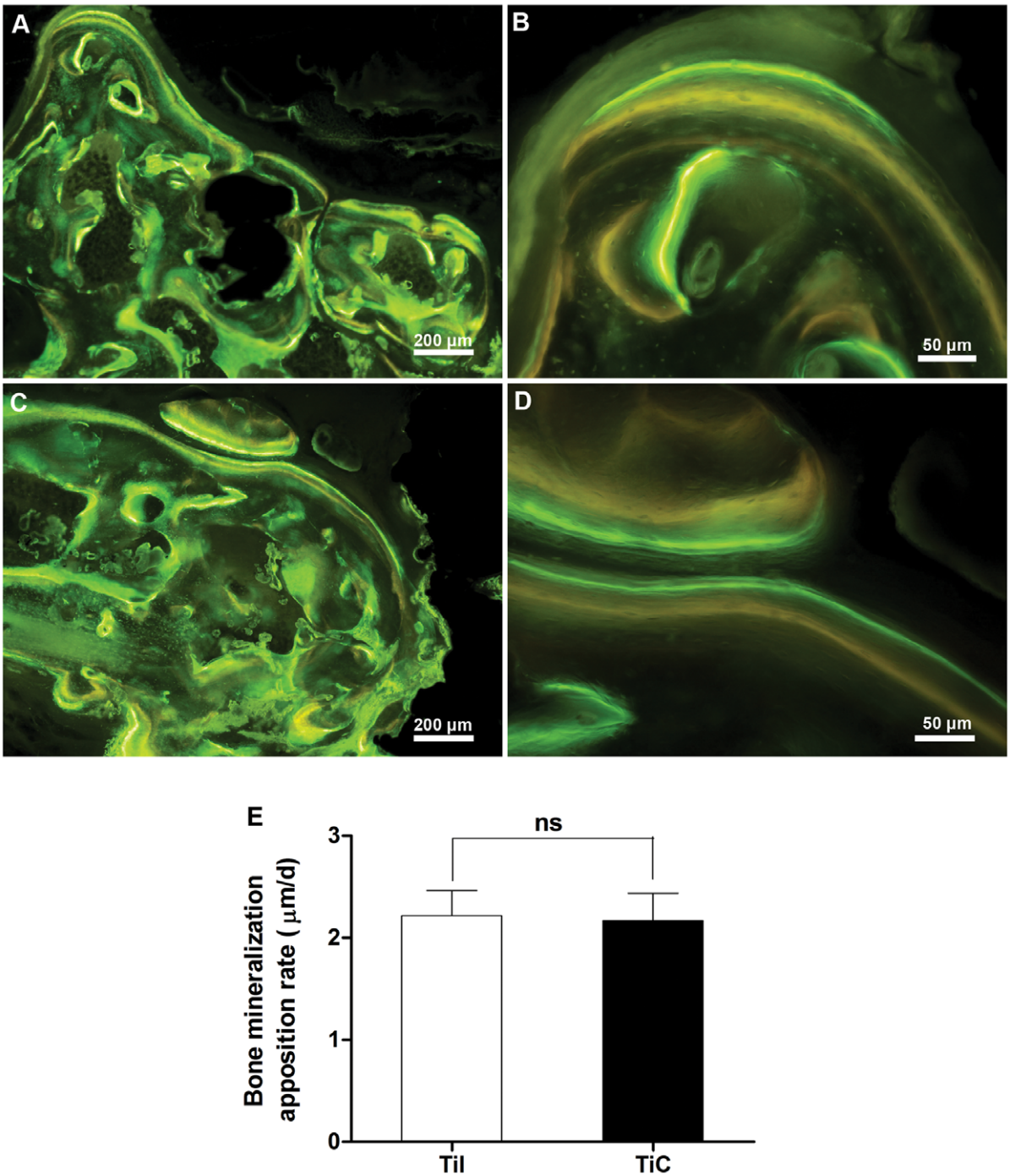

Figure 8. Fluorochrome labeling of bone regeneration at 12 weeks post surgery. The fluorescent labeling indicated that abundant new bone growth into the porous titanium and continuous process of bone remodeling in both (**A B**) uncoated and (**C D**) coated samples. (**E**) The rate of bone mineralization apposition was similar in these two kinds of porous titanium at 12 weeks post surgery ($P>0.05$). Til, pure porous titanium implant; TiC, porous titanium implant with biomimetic coating.
doi:10.1371/journal.pone.0052049.g008

requirements may lead to the conflicting design goals. Hollister et al. [33,34] developed a general design optimization scheme for the pore architecture to match desired elastic properties and porosity simultaneously, by introducing the homogenization based topology optimization algorithm. Furthermore, they demonstrated the prototypes of the designed structures which can be fabricated using additive manufacturing technique. Various porous structures cause different mechanical properties. Generally speaking, with increase of the porosity, the mechanical properties such as stiffness and compressive strength decreased [14]. It was found that not only porosity has an influence on the mechanical properties of porous samples, but also the pore size and orientation, and strut size of samples affect the mechanical properties [12,14]. In current study, we pre designed the porosity, pore size, and strut size of

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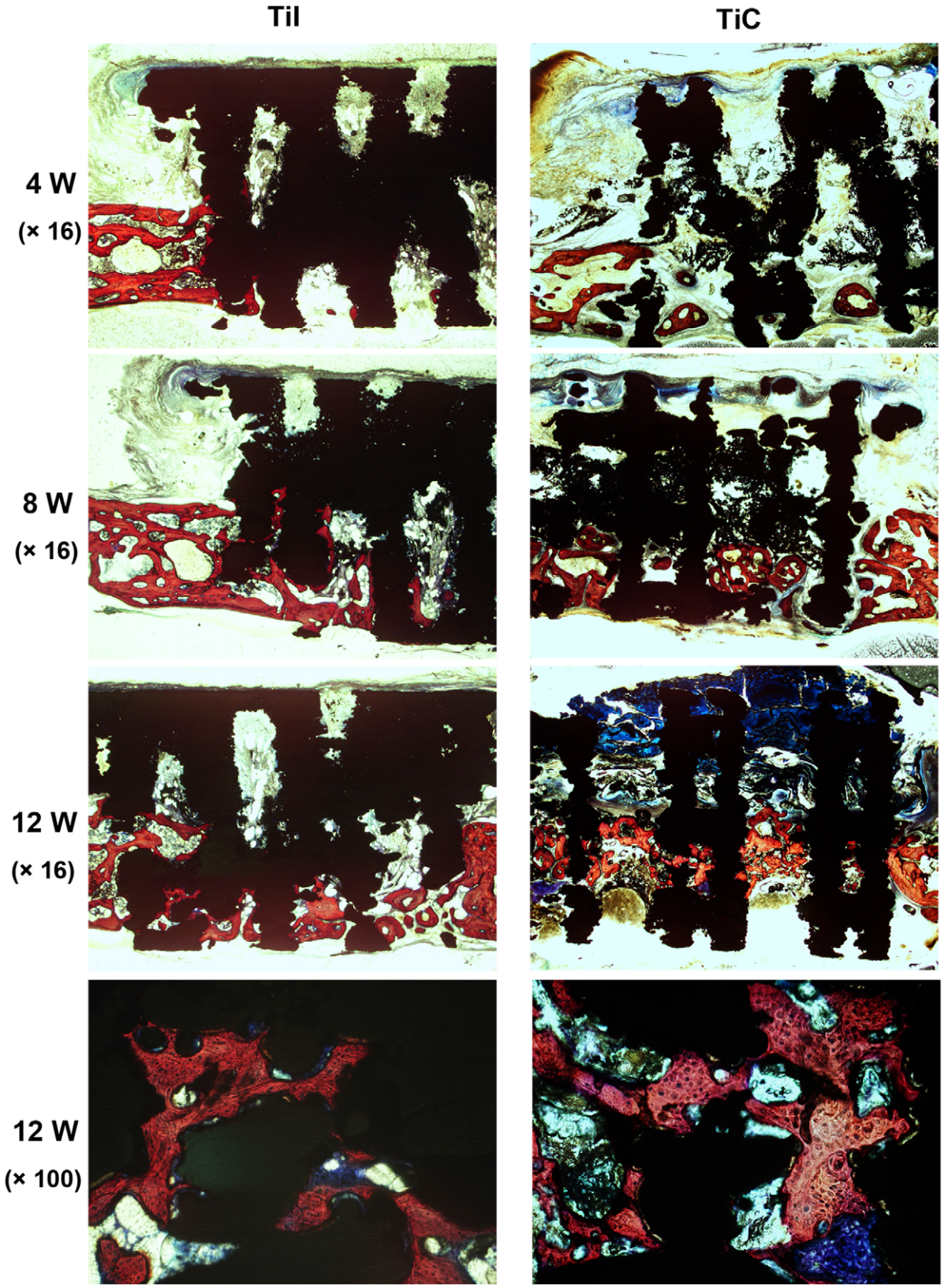

Figure 9. Histological staining for osteogenesis within porous titanium after implantation for 4, 8 and 12 weeks. The images showed that the rapid increase of bone ingrowth into the pores of titanium throughout the experiment and close contact between bone tissue and EBM implants at 12 weeks post surgery, while there were no obvious differences between the uncoated and coated samples at each timepoint. Til, pure porous titanium implant; TiC, porous titanium implant with biomimetic coating.
doi:10.1371/journal.pone.0052049.g009

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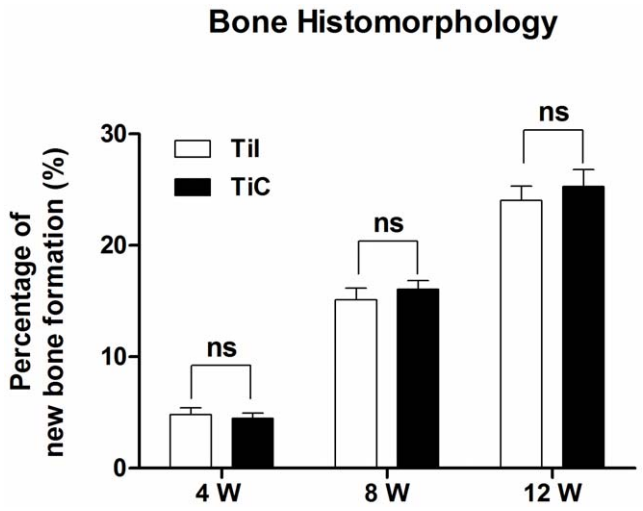

Figure 10. Histomorphometric analysis of new bone formation. The data showed a high percentage of newly formed bone in the defect region in both coated and uncoated implants during the whole experiment ($P>0.05$). TiI, pure porous titanium implant; TiC, porous titanium implant with biomimetic coating.
doi:10.1371/journal.pone.0052049.g010

samples to adjust the mechanical properties to match that of cortical bone. The EBM produced porous Ti6Al4V implants showed a favorable mechanical property (compressive strength range from 163 286 MPa, Young's modulus range from 14.5 38.5 GPa) and suitable porous structure (fully interconnected porous networks, porosity range from 51 61%, the pore size range from 500 600 μm) for the load bearing application in treating large segmental bone defects.

The biomimetic technique allowed the homogeneous deposition of a carbonated apatite layer onto the porous metallic implants [14,25]. This coating has a composition and crystallinity index similar to that of bone mineral [23]. Jalota et al. investigated the proliferation of osteoblast on neat and bone like apatite coated surfaces of titanium foams and found that bone like apatite coated surfaces exhibited the highest protein production and cell attachment [35]. It was revealed that the direct bone contact was significantly higher for bone like apatite coated dense Ti6Al4V than the corresponding uncoated implants [25].

As one part of our study design, the biomimetic approach was used to deposit bone like apatite on porous samples surfaces to promote the attachment, migration and proliferation of osteoblasts on the samples. However, no significant differences were observed in osteoblast function and morphology on the porous scaffolds between groups with or without biomimetic coatings. Ponader et al. reported that topographical surface modifications of electron beam melted Ti 6Al 4V titanium markedly influenced the function of human fetal osteoblasts [36]. The interactions between cells and microtopography of scaffold have been extensively studied, suggesting that microtopographies can promote bone to implant contact via such mechanisms as mechanical interlocking [37] and enhancement of osteoblast functions [38]. Cells can well communicate and in consequence proliferate as long as there is enough space to attach on the relatively smooth surface [39], while the peaks on the rough surfaces of implants may offer more favorable biological environment for the adhesion and differentiation of osteoblasts [40,41]. The EBM titanium in the present study consist of Ti6Al4V powders (particle size: 45 100 μm) [12] which provide mild undulant surfaces without high peaks and scarped flanks, making it suitable matrix to trigger the attachment and proliferation of osteoblasts.

The in vivo experiment revealed that bone had started to grow from the host bone bed to the porous implants. The penetration depth of new bone regeneration increased rapidly with the implantation time, and eventually bridged the defect at week 12, demonstrating excellent osteoconductivity of the Ti6Al4V implants fabricated by EMB process. The amount of formed bone of EBM Ti 6Al 4V titanium in our study was much higher than that of porous titanium manufactured by other methods [29], and was comparable to that of EBM porous titanium reported by other study [31]. Takemoto et al. reported that the bioactive porous titanium achieved bone ingrowth to a depth of 3 mm within 4 weeks of implantation and continued to increase throughout the 16 weeks of implantation, whereas bone ingrowth into the nontreated implants tended to decrease between 4 and 8 weeks [42], whereas the pure EBM porous titanium used in our study exerted remarkable and continuous increase of bone formation throughout the whole experiment. Although several studies suggested that it might be necessary to improve the biological performance of titanium implant by being treated chemically and thermally, and/or coated with bioactive materials [43,44,45], it was similar for the new bone ingrowth within the implants with and without apatite coating. It was revealed that the properties that were considered as the important requirements for bone ingrowth contained favorable topographical surface for cell adhesion and proliferation, interconnected porous structures in all dimensions, appropriate mechanical strength corresponding to those of native bone [14,31,36]. In this study, it looks like the adequate architecture and mechanical properties of EBM porous scaffolds may contribute mainly to the optimized ingrowth of surrounding bone tissue in addition to the surface modification.

Conclusion

EBM technique can be used to fabricate Ti6Al4V implants with well controlled porous structures and favorable mechanical properties, which is close to native bone tissue. This Ti6Al4V implants presented good cell attachment and proliferation properties in vitro, as well as satisfied bone ingrowth and direct bonding between host bone tissue and the implants. Biomimetic approach can be utilized to coat the porous Ti6Al4V implants with a homogenous layer of bone like apatite, whereas this biomimetic coating did not further enhance the bioactivities of the titanium scaffolds. Therefore, porous Ti6Al4V implant fabricated by EBM technique possesses great potential for the clinical applications, which can not only reduce the mechanical mismatch but also achieve stable long term fixation by promoting bone ingrowth. This study opens up the possibility of using high strength porous scaffolds with appropriate osteoconductive and osteogenic properties to reconstruct bone defects on specific sites in the maxillofacial and orthopedic fields.

Acknowledgments

We thank Professor Rong Lv for providing helpful advice of the histology.

Author Contributions

Conceived and designed the experiments: LW XL YFF ZYZ. Performed the experiments: XL YFF GCL LW. Analyzed the data: YFF XL. Contributed reagents/materials/analysis tools: CTW GCL WL. Wrote the paper: XL YFF ZYZ LW. Revised the manuscript: XL LW WL.

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ATTACHMENT E

Carla Maria Haslauer, Jessica Collins Springer, Ola L.A. Harrysson, Elizabeth G. Loboa, Nancy A. Monteiro-Riviere, Denis J. Marcellin-Little, In vitro biocompatibility of titanium alloy discs made using direct metal fabrication, Medical Engineering & Physics, Volume 32, Issue 6, July 2010, Pages 645-652, ISSN 1350-4533, http://dx.doi.org/10.1016/j.medengphy.2010.04.003.

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Medical Engineering & Physics 32 (2010) 645–652

Contents lists available at ScienceDirect

Medical Engineering & Physics

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In vitro biocompatibility of titanium alloy discs made using direct metal fabrication

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J Biomater Appl published online 29 December 2011
DOI: 10.1177/0885328211431857

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Long-term biocompatibility and osseointegration of electron beam melted, free-form–fabricated solid and porous titanium alloy: Experimental studies in sheep

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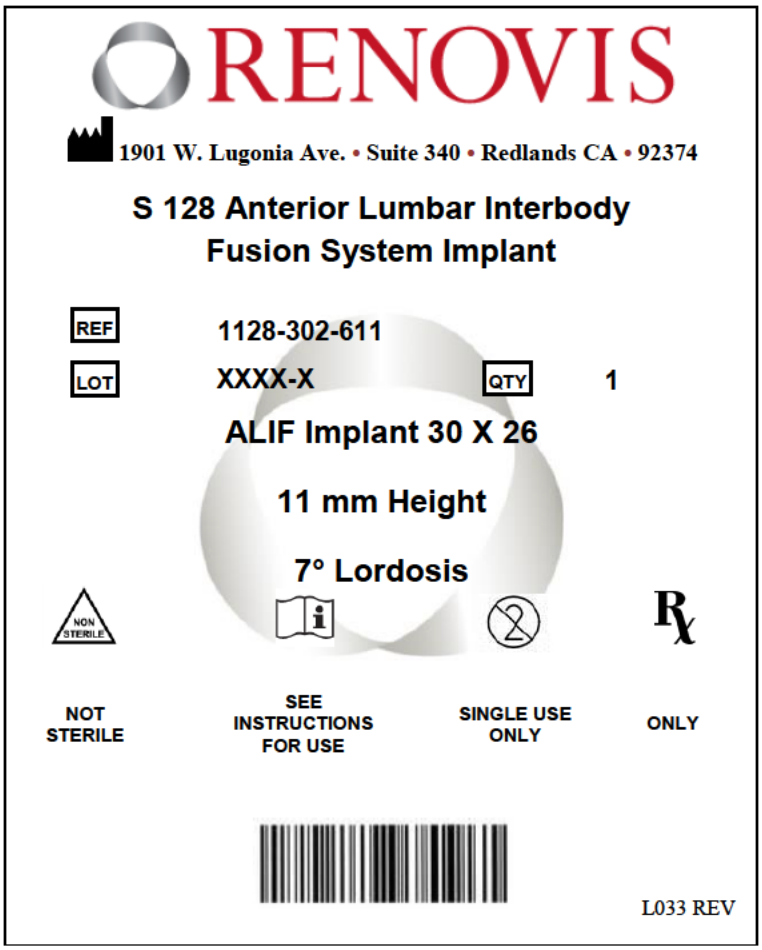
Labeling

9. You have provided a draft package label with the symbol "Rx" accompanied by the phrase "sale by physician prescription only". However, per 21 CFR 801.109(b)(1), the label should state "Caution: Federal law restricts this device to sale by or on the order of a physician" or it should contain the symbol "Rx only". Please provide a revised package label with the correct wording and/or symbol.

MEDIcept response:

The package labels have been revised as requested:

Label 1 Example of implant label



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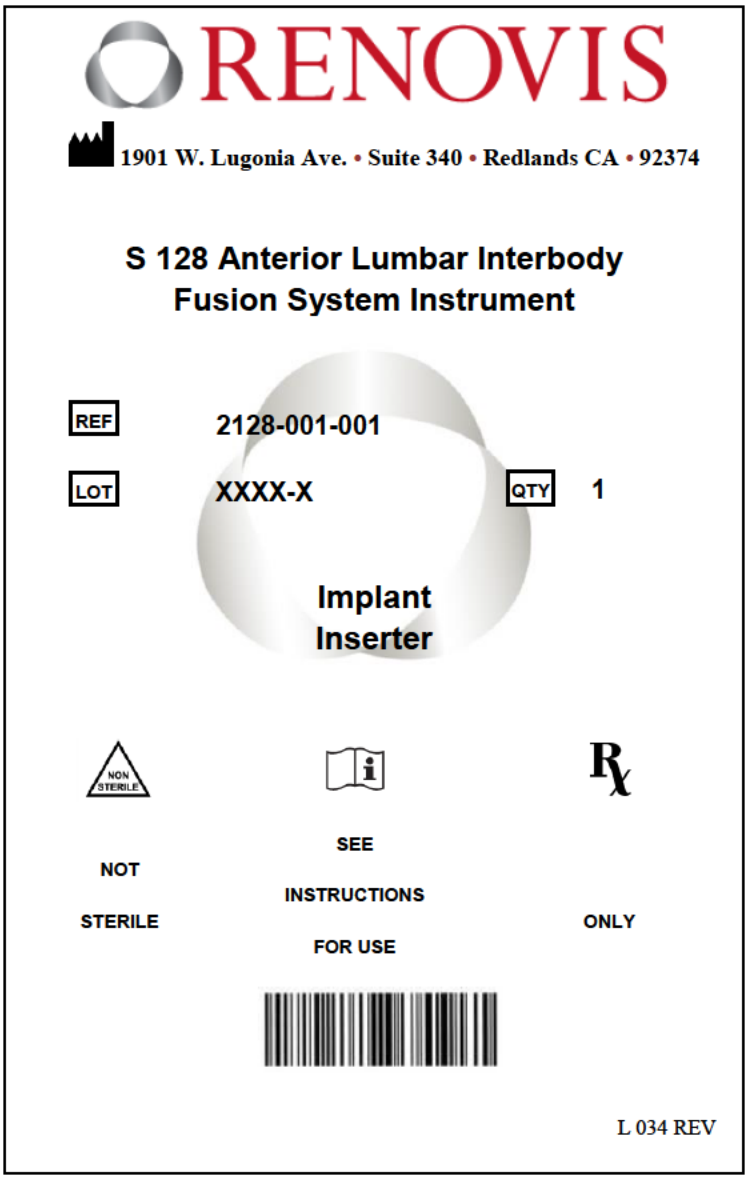
Label 2 **Example of Instrument Label**



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RENOVIS

Abbreviated 510(k) Summary
as required by 21 CFR 807.92(a)
K131122

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Date Prepared: July 25, 2013

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System

Device Class: Class II – 888.3080

Regulation and Product code: 888.3080, MAX - Intervertebral body fusion device

Classification panel: Orthopedic

C) Predicates:

- K081177 Blackstone Orthofix Pillar
- K092211 K2M Chesapeake
- K123767 Lanx Lateral –SA System
- K102738 Lanx Fusion System
- K083815 Lanx Fusion System
- K073144 Lanx Intervertebral Body Fusion Device
- K082260 Calvary Spine Petra PLIF Cage System

D) Device Description:

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

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The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is to be used with the bone screws and anterior cover plate assembly and requires no additional supplementary fixation

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systems. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The Renovis S128 ALIF System contains both fixed and variable angle screw options. The fixed angle screw option provides a tight fit with the cage. The variable angle screw option provides a slight clearance between the cage and the screw which allows for a small amount of variable screw angulations.

The Renovis S128 ALIF System cages are intended to be used with autogenous bone graft. The accompanying cover plate is designed to prevent screw back-out and must be used when the screws are implanted. NOTE: The cover plate assembly and screw are part of the implant construct.

The Renovis S128 ALIF System implants are available in a variety of sizes (widths, height, depths, and bone screw sizes) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and coverplate assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum. The Renovis S128 ALIF System is used with trials and implant specific manual instruments, and includes other class I manual orthopedic instruments.

E) Indications For Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

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F) Substantial Equivalence Comparison and Discussion

	Renovis S128 ALIF System	Blackstone (Orthofix) Pillar K081177	K2M Chesapeake K092211	Lanx Lateral SA System K123767 Fusions System K102738 Fusion System K083815 Intervertebral body Fusion Device K073144	Calvary Spine Petra PLIF Cage System K082260
Product code	MAX	MAX	MAX	MAX	MAX
Implant Material	PEEK Titanium	PEEK	PEEK	PEEK Titanium alloy	PEEK
Dimensions in mm A/P M/L H	 26, 28, 30 30, 34, 38 11 - 21	 28, 32 37, 40, 43 12.5 - 20	 24, 28, 30 30, 36, 40 11-19	 16, 18, 22, 26 25 to 60 6-16	 Crescent 13x 27 Straight 11 x 30 7-15
Lordosis	7°, 12°	7°, 12°	10^0, 15^0	0_0, $_{8}0$	$_{8}0$
Screw material	Titanium	Titanium	Titanium	Titanium when applicable	Requires supplemental fixation
Number of screws	4	4	3	Unk	
Screw Diameter (mm)	4.5, 5.0	5.0, 5.5	5.5	Unk	
Screw Length (mm)	20, 25, 30, 35	20, 25, 30, 35	20, 25, 30	Unk	
Cover plate	Titanium	Titanium	Titanium	Unk	
Marker material	Tantalum	Tantalum	Tantalum	Tantalum	Tantalum

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Conclusion

Based upon the same or similar intended use, design, function, technology, and materials, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

G) Performance Testing

The Renovis S128 ALIF System implants (worse case constructs) have successfully undergone the following testing:

1. Static Compression per ASTM F2077
2. Dynamic Compression per ASTM F2077
3. Static Shear-Compression per ASTM F2077
4. Dynamic Shear-Compression per ASTM F2077
5. Expulsion Testing w/screws per ASTM Draft Standard F04.25.02.02
6. Expulsion Testing w/o screws per ASTM Draft Standard F04.25.02.02
7. Subsidence testing per ASTM F2267

Sample coupons of the Titanium porous structure have successfully undergone the following testing:

1. Shear testing of metallic coatings per ASTM F1044
2. Tensile testing of metallic coatings per ASTM F1147
3. Abrasion per ASTM F1978
4. Porosity and microstructure per ASTM F1854

Conclusion

Performance data results support that the Renovis S128 ALIF System is substantially equivalent to the predicate devices and that there are no new issues of safety or effectiveness.

H) Compliance with FDA Guidance and Consensus Standards

The Renovis S128 ALIF System complies with the following:

FDA Guidance:

- Guidance Document Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", June 12, 2007.
- Guidance for Industry and FDA Staff: Spinal System 510(k)s", May 2004 for labeling including labels, Instructions for Use and Surgical Manual

21 CFR 888.3080 Intervertebral body fusion device:

- ASTM F 983-86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components

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- ASTM F 565-04 (Reapproved 2009)e1 Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- ASTM F2267-04 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression
- ASTM F2077-3 Test Methods for Intervertebral Body Fusion Devices

Other

- ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F-136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, and
- ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ASTM draft standard F.04.25.02.02 Static Expulsion
- ASTM F1044-05(2011)e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
- ASTM F1147- 05(2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
- ASTM F1978 – 12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser
- ASTM F1854 - Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants
- ASTM A564 - Standard Specification for Hot-Rolled and Cold-Finished Age-Hardening Stainless Steel Bars and Shapes
- ASTM F138 - Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants

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