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 23, 2016

Innovasis, Inc.
Mr. Marshall McCarty
Director QA/RA
614 East 3900 South
Salt Lake City, Utah 84107

Re: K162143
Trade/Device Name: FixxSure® X-Link
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: September 16, 2016
Received: September 19, 2016

Dear Mr. McCarty:

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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vincent J. Devlin -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K162143

Device Name
FixxSure® X-Link

Indications for Use *(Describe)*
The SpineWorks™ FixxSure® X-Link is intended to work with the Innovasis® Excella® Spinal System to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

i) Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra;
ii) Degenerative spondylolisthesis with objective evidence of neurologic impairment;
iii) Fracture;
iv) Dislocation;
v) Scoliosis;
vi) Kyphosis;
vii) Spinal tumor; and
viii) Previous failed fusion (pseudarthrosis).

The SpineWorks™ FixxSure® X-Link can also be used with the Talon® Pedicle Screw System.*

*Talon® is a Registered Trademark of Amendia, Inc.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FixxSure® X-Link

510(k) Summary Report

FixxSure® X-Link (Updated 15 September 2016)

Company: Innovasis, Inc.
614 E. 3900 South
Salt Lake City, UT 84107

Contact: Marshall C. McCarty
Phone: (801) 261-2236
mmccarty@innovasis.com

Trade Name: FixxSure® X-Link

Common Name: Pedicle Screw System X-Link

Classification: 21 CFR 888.3070 Pedicle screw spinal system
Class II
Product Code: MNH, MNI
Review Panel: Orthopedic-Posterior Spine Devices Brand (PSDB)

Purpose of Submission: Change in intended use.

Applicable Standards:

Acronym	Standard / Authorities / Bodies
AAMI	American Association of Medical Instrumentation
ASTM	American Society for Testing and Materials
CFR	Code of Federal Regulations
FDA CDRH	Food and Drug Administration Center for Device and Radiological Health
ISO	International Organization for Standardization

Standard Citation	Title
Regulatory Standards and Guidance – Medical Devices	
ANSI BS EN ISO 13485: 2012	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
21 CFR Part 801	U.S. FDA, Code of Federal Regulations, Labeling
21 CFR Part 820	U.S. FDA, Code of Federal Regulations, Quality System Regulation
FDA CDRH Guidance	Guidance for Industry and FDA Staff: Spinal Systems 510(k)s
FDA CDRH Guidance	Guidance for Industry and for FDA Staff: Use of Standards in Substantial Equivalence Determinations
ASTM F136-13	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

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FixxSure® X-Link

Standard Citation	Title
ASTM F983-86 (R2009)	Standard Practice for Permanent Marking of Orthopaedic Implant Components
ASTM F1582-98 (R2011)	Standard Terminology Relating to Spinal Implants
ASTM F1717-15	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
Risk Analysis and Design Control: Standards and Guidance	
AAMI ANSI ISO 14971:2007/(R)2010	(Corrected 4 October 2007) Medical Devices – Application of Risk Management to Medical Devices
FDA CDRH Guidance	Design Control Guidance for Medical Device Manufacturers
Biocompatibility Evaluations: Standards and Guidance	
ANSI/AAMI/ISO 10993-1:2009 & Cor 1:2010	Biological Evaluation of Medical Devices
Sterilization Methods: Standards and Guidance	
AAMI TIR12:2010	Design, Testing and Labeling Reusable Medical Devices for Re-processing in Health Care Facilities
ANSI/AAMI ST79:2010 & A1:2010	Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
ISO 17665-1: 2006	Sterilization of Healthcare Products – Moist Heat – Part 1 Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices

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FixxSure® X-Link

Primary Predicate: K081331 SpineWorks *FixxSure*® X-Link
This predicate has not been subject to a design-related recall.

Additional Predicates: K140238 Innovasis *Excella III-D*® Spinal System
K032739 SeaSpine Crossbar

Device Description: The SpineWorks *FixxSure* X-Link is a transverse stabilizing device utilized to increase the strength of a pedicle screw instrumentation construct in posterior spinal fusion. The *FixxSure* implant comes in multiple lengths and has the capability of being manipulated into various planes of angulation. The *FixxSure* implant has a proprietary dual locking mechanism allowing maximum cross-Link/rod connection while maintaining ease of insertion/use.

Performance Data: (Non-clinical)—Testing was performed in accordance with ASTM F1717-14, "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model." Two *Excella II* pedicle screw constructs with the *FixxSure X-Link* were tested per F1717 for dynamic compression bending at 175N (7.0Nm) and 5Hz. Both constructs successfully completed 5,000,000 cycles.

Materials: The components in this submission are fabricated from Ti-6Al-4V alloy, conforming to ASTM F136, which is known to have good biocompatibility.

Intended Use: The Innovasis *SpineWorks* brand *FixxSure X-Link* is intended to work with the Innovasis® *Excella*® *Spinal System* to provide immobilization and stabilization of spinal segments during the fusion process.
Users of these products are limited to physicians trained in orthopedic surgery. Clinical locations include hospitals and surgery sites equipped to perform spinal surgery.

Indications for Use: The SpineWorks *FixxSure X-Link* is intended to work with the Innovasis® *Excella*® *Spinal System* to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

i) Severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra;
ii) Degenerative spondylolisthesis with objective evidence of neurologic impairment;
iii) Fracture;
iv) Dislocation;
v) Scoliosis;
vi) Kyphosis;
vii) Spinal tumor; and
viii) Previous failed fusion (pseudarthrosis).

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The SpineWorks FixxSure X-Link can also be used with the Talon® Pedicle Screw System.*

Basis for Substantial Equivalence:

The SpineWorks *FixxSure X-Link* was cleared by FDA on July 23, 2008 under K081331. Innovasis acquired this product from SpineWorks, LLC in 2014, and has legal ownership of the brand name (SpineWorks) and the device cleared under K081331.

The Innovasis *Excella III-D* Spinal Deformity System was cleared by FDA on May 7, 2014 under K140238. This system included the *Universal X-Link,* which was a design upgrade of the cross link cleared October 7, 2010 under K102248. The primary difference in these two implants is the ability of the Universal X-Link to work with both 6.0 and 5.5mm rods.

The technological characteristics were found to be substantially equivalent in terms of design, sizes, materials (biocompatibility profile and processing), and mechanical strength.

Conclusion: The conclusions drawn from the nonclinical tests demonstrate that the subject device is substantially equivalent to the legally marketed predicate device.