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

February 16, 2017

Providence Medical Technology, Inc.
Mr. Edward Liou
Chief Operating Officer
1331 North California Boulevard, Suite 320
Walnut Creek, California 94596

Re: K163374
Trade/Device Name: ALLY™ Facet Screws
Regulatory Class: Unclassified
Product Code: MRW
Dated: January 17, 2017
Received: January 19, 2017

Dear Mr. Liou:

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

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

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

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

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,

Mark N. Melkerson -S

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)*
K163374

Device Name
ALLY™ Facet Screws

Indications for Use *(Describe)*

The ALLY™ Facet Screws are indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels:

1) Trauma, including spinal fractures and/or dislocations;
2) Spondylolisthesis;
3) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity; and
4) Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

The ALLY™ Facet Screws provide temporary stabilization as an adjunct to spinal fusion.

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.

510(k) SUMMARY

Providence Medical Technology, Inc.'s ALLY™ Facet Screws

Date Prepared: February 8, 2017

Company: Providence Medical Technology, Inc.
1331 N. California Blvd., Suite 320
Walnut Creek, CA 94596

Contact Person: Edward Liou
Phone: 415.923.9376
Facsimile: 415.923.9377

Trade Name: ALLY™ Facet Screws

Common Name: Facet screw

Classification Name: System, Facet Screw Spinal Device

Product Code, Class: MRW, Unclassified

Predicate Devices:

Primary Predicate: Spartan^{S3} Facet System (K092568, cleared 11/17/09)
(This device has not been subject to recall.)

Additional Predicates: Venus Facet Screw System (K120340, cleared 10/19/12)
Facet Fixx (K131417, cleared 7/12/13)

Indications for Use:

The ALLY™ Facet Screws are indicated for the posterior surgical treatment of any or all of the following at the C2 to S1 (inclusive) spinal levels:

1) Trauma, including spinal fractures and/or dislocations;
2) Spondylolisthesis;
3) Pseudoarthrosis or failed previous fusions which are symptomatic or which may cause secondary instability or deformity;
4) Degenerative diseases which include: (a) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by patient

history with degeneration of the disc as confirmed by radiographic studies and/or (b) degenerative disease of the facets with instability.

The ALLY™ Facet Screws provide temporary stabilization as an adjunct to spinal fusion.

Device Description

The ALLY™ Facet Screws are permanent implant devices manufactured from Titanium-6AL-4V ELI. The device is available in a variety of diameters and lengths to accommodate patient anatomy. The device is intended to provide mechanical support and stability to the implanted level until biologic fusion is achieved. The device is supplied sterile and single-use only.

Technological Characteristics.

The ALLY™ Facet Screws have technical characteristics similar to the predicate devices. See table below for a comparison of technical attributes.

Technological Characteristics	
ALLY™ Facet Screws (Subject Device)	**Spartan S^3 Facet System (Predicate Device)**
Single use only implant	Same
Supplied sterile, individually packaged	Same
Implant material is 6Al-4V Titanium conforming to ASTM F136	Same
Fully threaded and lag versions	Same
Self-drilling and self-tapping	Same

Performance Testing

The following testing was performed using the subject device and results were compared to those of the predicate device:

Static and Dynamic Cantilever Bending

- ASTM F2193-14 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System

Static Torsion Testing

- ASTM F543-13 Standard Specification and Test Methods for Metallic Medical Bone Screws

Static Pull-Out Testing

- ASTM F543-13 Standard Specification and Test Methods for Metallic Medical Bone Screws

Drive Torque

ASTM F543-13 Standard Specification and Test Methods for Metallic Medical Bone Screws

In addition, the following testing was performed:

Pyrogenicity Testing

- Pyrogenicity Testing was conducted in compliance with the FDA Guidance Documents listed below:
  - "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile: Guidance for Industry and Food and Drug Administration Staff"
  - "Pyrogen and Endotoxins Testing: Questions and Answers"
  - Bacterial endotoxin testing (BET) as specified in USP <85> is used for pyrogenicity testing to achieve the Endotoxin limit of <20EU/Device.

In all instances, the ALLY™ Facet Screws functioned as intended and met all pre-determined acceptance criteria. Bench testing results of the ALLY™ Facet Screws exceeded those of the predicate Spartan S^3 Facet System. Therefore, the performance characteristics of the ALLY™ Facet Screws are substantially equivalent to those of the Spartan S^3 Facet System.

Substantial Equivalence

The ALLY™ Facet Screws (subject device) are substantially equivalent to the Spartan S^3 Facet System (predicate device cleared under K092568). When compared to the predicate device, the ALLY™ Facet Screws have the same:

- indication for use;
- implant material (Ti 6Al-4V ELI);
- design characteristics (fully threaded and lag versions);
- operating principle; and
- insertion method (via posterior spine).

The subject devices are offered in a larger size range than that of the predicate device however, the ALLY™ Facet Screws are offered in the same size range as that of the reference devices. In addition, the Spartan S^3 Facet System is cannulated while the ALLY™ Facet Screws are not. This difference does not affect the outer thread features of the subject device and thus the functional differences between the two devices are considered very minor. These minor differences between the ALLY™ Facet Screws and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the ALLY™ Facet Screws are substantially equivalent to the Spartan S^3 Facet System.