**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

May 31, 2017

Providence Medical Technology, Inc.
Edward Liou
Chief Operating Officer
1331 N. California Blvd., Suite 320
Walnut Creek, California 94596

Re: K170698
Trade/Device Name: ALLY™ Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 17, 2017
Received: May 18, 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

## Indications for Use Statement

510(k) Number (if known): K170698

Device Name: ALLY™ Bone Screws

Indications for Use:

ALLY™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

# 510(k) SUMMARY

## Providence Medical Technology's ALLY™ Bone Screws

**Date Prepared:** May 26, 2017

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

**Contact Person:** Edward Liou
ed@providencemt.com
Phone: 415-923-9376
Fax: 415-923-9377

**Trade Name:** ALLY™ Bone Screws

**Common Name:** Bone screw

**Classification Name:** Screw, fixation, bone

**Regulation Number:** 21 CFR Part 880.3040

**Product Code:** HWC
**Class:** Class II

**Predicate Devices:**

**Primary Predicate:** PMT Bone Screws (K121713, cleared 09/27/2012)

**Reference Devices:** Orthohelix Surgical Designs, Inc.: CSS Cannulated Screw System (K060428, cleared 03/07/2006)

Wright Medical Technology, Inc.: WRIGHT™ Compression Screws (K082320, cleared 11/05/2008)

### Device Description

The ALLY™ Bone Screws are fully threaded cortical screws offered in various diameters and lengths. All screws are manufactured from titanium alloy. The implants are single use only.

### Indications for Use

The ALLY™ Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation appropriate for the size of the device.

**Technological Characteristics**

The ALLY™ Bone Screws have the following technological characteristics:

- Manufactured from Titanium Alloy
- Available headed, headless, or snap-off with various tip configurations
- Available in various diameters and lengths

**Performance Data**

The ALLY™ Bone Screws are evaluated for static torsion, static pull out, and driving torque testing per ASTM F543 Standard Specification and Test Methods for Metallic Bone Screws.

Engineering analysis for screw bending strength has been completed.

Bacterial Endotoxin testing (LAL) has been completed and shown to meet the device limits.

**Substantial Equivalence**

The ALLY™ Bone Screws are as safe and effective as the predicate device. The ALLY™ Bone Screws have the same indications for use, technological characteristics, and principles of operation as its predicate device. The reference devices are available in the extended size ranges being added to the ALLY™ Bone Screws.

Comparison between ALLY™ Bone Screws and its predicate devices raises no new issues of safety or effectiveness. The ALLY™ Bone Screws are substantially equivalent to the PMT Bone Screws.