



JAN 10 2014

## 510(k) Summary Annex™ Adjacent Level System

### 1. Submitter Information

Submitter: Spine Wave, Inc.  
 Address: Three Enterprise Drive  
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 Shelton, CT 06484  
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 Contact: Joseph Mercado  
 Date Prepared: December 12, 2013

### 2. Device Information

*Trade Name:* Annex™ Adjacent Level System  
*Common Name:* Pedicle Screw Spinal System  
*Classification Name:* Pedicle Screw Spinal System  
*Classification/ Code:* Class II per 21 CFR 888.3070 / MNH, MNI

### 3. Purpose of Submission

The purpose of this submission is to gain clearance for a new spinal fixation system.

### 4. Predicate Device Information

The Annex™ Adjacent Level System described in this submission is substantially equivalent to the following predicates:

Predicate Device	Manufacturer	510(k) No.
CapSure® PS System	Spine Wave, Inc.	K070245, K132154
Revere® Stabilization System	Globus Medical, Inc.	K122226
Synergy VLS Spine System	Interpore Cross International	K011437

### 5. Device Description

The Annex™ Adjacent Level System consists of a selection of non-sterile, single use connectors manufactured from titanium alloy (ASTM F136) and cobalt chrome alloy (ASTM F1537), for attachment to an existing 5.5mm diameter rod construct to extend a rigid spinal construct. The connectors are provided in a variety of sizes and shapes to

accommodate variations in anatomy and spacing/positioning of existing screw and rod hardware.

## **6. Intended Use**

When used with pedicle screw fixation systems of the noncervical spine in skeletally mature patients, the Annex™ Adjacent Level System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

The Annex™ Adjacent Level System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3-S1), and for whom the device is intended to be removed after solid fusion is attained.

The Annex™ Adjacent Level System can be linked to 5.5mm diameter rod systems, including the CapSure® or Sniper® Spine Systems.

## **7. Comparison of Technological Characteristics**

The substantial equivalence of the subject Annex™ Adjacent Level System to the predicates is shown by similarity in intended use, indications for use, materials and performance.

## **8. Performance Data**

Static axial compression bending, dynamic axial compression bending, and static torsion testing according to ASTM F1717 were performed to demonstrate that the subject Annex™ Adjacent Level System is substantially equivalent to the predicates.

## **9. Conclusion**

Based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the subject Annex™ Adjacent Level System has been shown to be substantially equivalent to the predicate devices identified in this submission, and does not present any new issues of safety or effectiveness.



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

January 10, 2014

Spine Wave, Incorporated  
Mr. Joseph Mercado  
Regulatory Affairs Specialist  
Three Enterprise Drive, Suite 210  
Shelton, Connecticut 06484

Re: K132403  
Trade/Device Name: Annex™ Adjacent Level System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: MNH, MNI  
Dated: December 12, 2013  
Received: December 13, 2013

Dear Mr. Mercado:

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  Jean -S for

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

Enclosure

**Indications for Use**

510(k) Number (if known)  
K132403

Device Name  
Annex™ Adjacent Level System

**Indications for Use (Describe)**

When used with pedicle screw fixation systems of the noncervical spine in skeletally mature patients, the Annex™ Adjacent Level System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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The Annex™ Adjacent Level System can be linked to 5.5mm diameter rod systems, including the CapSure® or Sniper® Spine Systems.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

**Zane W. Wyatt -S**