OCT 19 2012

## 510(K) SUMMARY

**Submitter Information**

Submitter's Name: Apollo Spine
Address: 3700 Campus Dr. Suite 105
Newport Beach, CA 92660
Telephone: 949-757-0406

Contact Person: Christine Santagate
Telephone : 781-828-4400

**Date Prepared:** October 18, 2012

**Device Trade Name:** Venus Facet Screw System

**Common/Usual Name:** Facet Screw System

**Classification:** Unclassified

**Product Code:** MRW

**Intended Use:**

The Apollo Spine Venus Facet System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 4.5mm and 5.5 mm screws. For transfacet fixation the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The Apollo Venus Facet System is indicated for treatment of any or all of the following:

- Pseudoarthrosis and failed previous fusions which are symptomatic or which may cause secondary instability or deformity
- Spondylolisthesis
- Spondylolysis

- Degenerative disk disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies
- Degeneration of the facets with instability
- Trauma including spinal fractures and/or dislocations

**Predicate Devices:**
The Venus Facet System was shown to be substantially equivalent to 'previously cleared devices and has the same indications for use and is similar in terms of design, function, and materials used. Cleared devices include the Perpos Percutaneous Cervical Facet Screw Bone-Lok Implant® (Triage Medical K052043), the Amendia™ Inc. Spartan $S^3$ Facet System (K092568), and the X-spine Fixcet Spinal Facet Screw System (K100154).

**Device Description**

**Device Identification:**
The Venus Facet Screw System consists of two separate diameter screws and is provided in variable lengths for cervical and lumbar use. The screws have small fenestration in the threaded portion. The product variants are provided in the following table:

**Table 10-1**
**Venus Facet System Dimensional Specifications**

| Diameter | Length | Part Number | Vertebral Levels |
|---|---|---|---|
| 4.5mm | 13mm | 50-10-203 | C2-S1 |
| | 15mm | 50-10-204 | C2-S1 |
| | 25mm | 50-10-205 | L1-S1 |
| | 35mm | 50-10-206 | L1-S1 |
| | 45mm | 50-10-207 | L1-S1 |
| 5.5mm | 13mm | 50-10-303 | C2-S1 |
| | 15mm | 50-10-304 | C2-S1 |
| | 25mm | 50-10-305 | L1-S1 |
| | 35mm | 50-10-306 | L1-S1 |

| Table 10-1 | | | |
|---|---|---|---|
| **Venus Facet System Dimensional Specifications** | | | |
| Diameter | Length | Part Number | Vertebral Levels |
| | 45mm | 50-10-307 | L1-S1 |

**Device Characteristics:**
The Venus Facet Screw System is an implanted device. The materials contained in the device include implant grade titanium alloy, Ti-6Al-4V (ELI) per ASTM F-136. The device is sold non-sterile and is to be sterilized at the end use facility by steam sterilization. The Venus Facet Screw System is a single use device.

**Environment of Use:**
The Venus Facet Screw System is used during surgical procedures conducted at a healthcare facility/hospital.

**Description:**
The system includes a cervical and lumbar facet screws. The system screws provide fixation and are designed to connect vertebral facets, resulting from such causes as degenerative disease and/or trauma. These screw kits are considered a 'family' product line with sizes based on the anatomical variations of the patient's facets.

**Materials of Use:**
The facet screws are machined from implant grade titanium alloy, Ti-6Al-4V (ELI) per ASTM F-136. The device is in contact with soft tissue and posterior spinal elements.

**Performance Standards:**
Performance testing and engineering analysis were conducted to characterize the performance of the Apollo Spine Venus Facet Screw System. Testing performed included dynamic and static three-point bend per ASTM F1264-03, cantilever bend per ASTM F2193, torsion and axial pull-out testing per ASTM F543. The device functioned as intended and the observed test results demonstrate substantial equivalence to the predicate devices.

**Performance and SE Determination:**
The Apollo Spine Venus Facet Screw System has the same or similar intended use, indications, principals of operation, and technological characteristics as the predicate systems. Mechanical testing and engineering analysis demonstrated comparable mechanical properties to the predicate devices. Equivalency of this device to the predicate devices is based on similarities in intended use, materials and design in combination with acceptable mechanical performance properties. Thus, the Apollo Spine Facet Screw System is substantially equivalent to the predicate devices.

**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

OCT 19 2012

Apollo Spine
% STD Med Incorporated
Ms. Christine Santagate
75 Mill Street
Stoughton, Massachusetts 02072

Re: K120340
Trade/Device Name: Venus Facet Screw System
Regulatory Class: Unclassified
Product Code: MRW
Dated: September 26, 2012
Received: September 27, 2012

Dear Ms. Santagate:

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 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,

For

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

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K120340

Device Name: Venus Facet Screw System

Indications for Use:

The Apollo Spine Venus Facet Screw System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints, with or without bone graft, at single or multiple levels, from C2 to S1 for 4.5mm and 5.5 mm screws. For transfacet fixation the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The Apollo Venus Facet Screw System is indicated for treatment of any or all of the following:

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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 IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K120340