510(k) Summary
for the VENUS Anterior Cervical Plate

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the VENUS Anterior Cervical Plate.

Date Prepared: December 28, 2010

FEB 10 2011

1. **Submitter:**
Verticor, LTD
600 N. Marienfeld Street, Suite 350
Midland, TX 79701
Telephone: 432-697-7463

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** VENUS Anterior Cervical Plate
Common Name: Anterior cervical plate
Classification Name: Spinal intervertebral body fixation orthosis
21 CFR 888.3060
Class II
KWQ

3. **Predicate or legally marketed devices which are substantially equivalent:**
Spider Cervical Plating System [X-Spine Systems, K052292]
ORIA ZENITH [Eurosurgical, SA, K030500/K001535]
Synthes Anterior CLSP System [Synthes Spine, K000536/K945700]
Trestle Anterior Cervical Plating System [Alphatec, K102820]
SmartLOX Anterior Cervical Plate [Captiva,]

4. **Description of the device:**
The VENUS Anterior Cervical Plate is intended for anterior screw fixation to the cervical spine. The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and self-drilling bone screws using an anterior approach. Plates are available in a variety of lengths, addressing multiple levels of fixation. Bone screws are available for fixed angle or variable angle implantation in a variety of lengths and diameters. Each screw head forms an autogenic lock to the plate upon insertion, requiring no additional locking mechanism.

Materials:
The plates and screws are manufactured from titanium alloy (Ti 6Al 4V ELI) per ASTM F136. The screw retainer clip is fabricated from medical grand nitanol SE 508.

5. **Substantial equivalence claimed to predicate devices**
With regards to the intended use, material, design, characteristics and dimensions, the equivalence was determined through the points on the following pages.

Device Name / Items	VENUS Anterior Cervical Plate	Spider Cervical Plating System	ORIA ZENITH	CSLP
Sponsor	Verticor, LTD	X-Spine Systems	Eurosurgical, SA	Synthes Spine
510(k) Number	N/A	K052292	K030500/K001535	K000536/K945700
Plate material	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136
# Levels	Four	Four	Four	Four
Plate lengths	22mm – 92mm	22mm – 92mm	23mm – 97mm	25mm – 111mm

Items \ Device Name	VENUS Anterior Cervical Plate	Spider Cervical Plating System	ORIA ZENITH	CSLP
Retained screws	Yes	Yes	Yes	Yes
Bone graft window	yes	yes	yes	yes
Screw material	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136
Screw Ø	Ø4.0mm & Ø4.4mm	Ø4.0mm & Ø4.25mm	Ø4.0mm	Ø4.0mm
Screw length	12mm – 20mm	12mm – 16mm	?	13.5mm – 17.5mm
Self tapping screw	Yes	Yes	Yes	?

Items \ Device Name	VENUS Anterior Cervical Plate	Trestle Anterior Cervical Plating System	SmartLOX Anterior Cervical Plate	Anterior Cervical Compression System
Sponsor	Verticor, LTD	Alphatec	Captiva	Synthes
510(k) Number	N/A	K102820		K031276/K033844
Plate material	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136	Titanium alloy per ASTM F136
Nitinol Locking Mechanism	Yes	Yes	Yes	--
Screw Ø	Ø4.0mm & Ø4.4mm	--	--	Ø4.0mm & Ø4.5mm
Screw length	12mm – 20mm	--	--	12mm – 20mm

6. **Intended Use:**

The VENUS Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors,
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudarthrosis,
- failed previous fusion,
- spinal stenosis.

WARNING: The VENUS Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

7. **Non-clinical Test Summary**

Tests performed according to ASTM F2077 indicate that the VENUS Anterior Cervical Plate meets required mechanical strengths.

8. **Clinical Test Summary**

No clinical studies were performed

9. Conclusions Nonclinical and Clinical

The VENUS Anterior Cervical Plate has the same indications and material, and similar design as previously cleared 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

Verticor, Ltd.
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Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

FEB 10 2011

Re: K103137
Trade/Device Name: VENUS Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 31, 2010
Received: January 04, 2011

Dear Mr. Webb:

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,

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

510(k) Number (if known): K103137

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K103137