



August 23, 2016

Astura Medical  
% J.D. Webb  
President  
The OrthoMedix Group, Incorporated  
1001 Oakwood Boulevard  
Round Rock, Texas 78681

Re: K160702

Trade/Device Name: ZION Anterior Cervical Fixation System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: KWQ  
Dated: August 17, 2016  
Received: August 18, 2016

Dear J.D 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 Parts 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" (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 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,

**Vincent J. Devlin -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)

K160702

Device Name

ZION Anterior Cervical Fixation System

Indications for Use (Describe)

The ZION Anterior Cervical Fixation 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 T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) trauma (including fractures or dislocations), 4) tumors, 5) deformity (defined as kyphosis, lordosis, or scoliosis), 6) pseudarthrosis, 7) failed previous fusions and/or 8) spinal stenosis.

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)

**510(k) Summary: ZION Anterior Cervical Fixation System**

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

<b>Date Prepared</b>	May 20, 2016
<b>Submitted By</b>	Astura Medical 5670 El Camino Real, Suite B Carlsbad, CA 92008 760-814-8047 Tele email: info@asturamedical.com
<b>Contact</b>	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
<b>Trade Name</b>	ZION Anterior Cervical Fixation System
<b>Common Name</b>	anterior cervical plate
<b>Classification Name</b>	Spinal intervertebral body fixation orthosis
<b>Class</b>	II
<b>Product Code</b>	KWQ
<b>CFR Section</b>	21 CFR section 888.3060
<b>Device Panel</b>	Orthopedic
<b>Primary Predicate Device</b>	Zimmer Trinica/Trinica Select Anterior Cervical Plate (K132012)
<b>Secondary Predicate Devices</b>	Spinal USA Slimplicity Anterior Cervical Plating System (K060025) Biomet C-TekV MaxAnrm Anterior Cervical Plate System (K080646) Synthes CLSP Cervical Plate (K000536) DePuy UNIPLATE Anterior Cervical Plate (K042544 / K082273 / K100070)
<b>Device Description</b>	The Astura Medical ZION Anterior Cervical Fixation System is intended for anterior screw fixation of the plate 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 or self-drilling bone screws using an anterior approach. Plates are available in a variety of lengths addressing multiple levels of fixation. The ZION ACFS plate incorporates graft windows on the longitudinal center line for intraoperative visualization and for screw fixation of bone graft. Fixed or variable bone screws are available in two diameters and a variety of lengths, with self-tapping or self-drilling thread options.

<b>Materials</b>	Titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 Nitinol conforming to ASTM F2063
<b>Substantial Equivalence Claimed to Predicate Devices</b>	The ZION Anterior Cervical Fixation System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
<b>Indications for Use</b>	The ZION Anterior Cervical Fixation 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 T1). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) spondylolisthesis, 3) trauma (including fractures or dislocations), 4) tumors, 5) deformity (defined as kyphosis, lordosis, or scoliosis), 6) pseudarthrosis, 7) failed previous fusions and/or 8) spinal stenosis.
<b>Non-clinical Test Summary</b>	<p>The following analyses were conducted:</p> <ul style="list-style-type: none"> <li>• Static and dynamic compression testing per ASTM F1717</li> <li>• Static torsion testing per ASTM F1717</li> <li>• Corrosion testing (ASTM F2129)</li> </ul> <p>The results of these evaluations indicate that the ZION Anterior Cervical Fixation System is equivalent to the predicate devices.</p>
<b>Clinical Test Summary</b>	No clinical studies were performed
<b>Conclusions: Non-clinical and Clinical</b>	Astura Medical considers the ZION Anterior Cervical Fixation System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.