

**510(K) Summary**

(21 CFR Part 807.92)

K070638

A. Submitter Information

Submitter's Name: Theken Spine, LLC  
 Address: 283 E. Waterloo  
 Akron, Ohio 44319  
 Telephone Number: 330-773-7677 x221  
 Fax Number: 330-773-7697  
 Contact Person: Dale Davison  
 Date Prepared: 05 March 2007

MAY 30 2007

B. Device Information

Trade Name: Atoll™ Cervico-Thoracic System

Common Name: Posterior Cervical Instrumentation

Classification: **Class II System with the corresponding product codes:**  
**KWP 888.3050 - Spinal Interlaminar Fixation Orthosis**  
**MNI 888.3070(b)(1) – Pedicle Screw Spinal System**

Predicate Device: Synthes (USA) – Cervifix System (K990965)/Starlock System  
 Medtronic Sofamor Danek USA, Inc. – VERTEX Reconstruction System (K003780)  
 DePuy-AcroMed, Inc.-Summit Occipito-Cervico-Thoracic (OCT) Spinal System (K002733)

Material Composition: Implant Grade Titanium Alloy (Ti-6Al-4V) per ASTM F136 and ISO 5832-3

Subject Device Description: The Atoll Cervico-Thoracic System is intended for use as an aid in spine fusion. It consists of screws, hooks, rods, and connectors. These components are available in a variety of sizes to allow for a variety of configurations to better fit each individual patient physiology.

The Atoll Cervico-Thoracic System components are manufactured from medical implant grade titanium alloy Ti-6Al-4V (ELI) per ASTM F136 and ISO 5832-3.

To achieve the best results, unless otherwise specifically described in another Theken Spine document, do not use Atoll Cervico-Thoracic System components in conjunction with components for any other system or manufacturer.

Intended Use: The Atoll Cervico-Thoracic System is indicated to promote fusion of the cervico-thoracic regions of the spine (C1 – T3). The intended indications are as follows:

- Degenerative Disc Disease (as identified by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis

- Spinal Stenosis
- Fracture/Dislocation
- Deformities or Curvature
- Tumors
- Pseudoarthrosis
- Revision of previous cervical and upper thoracic spine surgery

The use of the screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The screws are not intended for use in the cervical spine.

The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

### C. Substantial Equivalence

The characteristics of the Atoll Cervico-Thoracic System are similar to the following predicate devices:

1. CerviFix System (K990965)/Starlock System manufactured by Synthes (USA) and cleared by the FDA on July 1, 1999.
2. VERTEX™ Reconstruction System (K003780) manufactured by Medtronic Sofamor Danek USA, Inc. and cleared by the FDA on September 28, 2001
3. Summit OCT Spinal System (K002733) manufactured by DePuy AcroMed, Inc and cleared by the FDA on December 15, 2000.

Equivalence for the Atoll Cervico-Thoracic System is based on similarities of intended use, design, and physical characteristics when compared to the predicate devices. Therefore, Theken Spine believes that there is sufficient evidence to conclude that the Atoll Cervico-Thoracic System is substantially equivalent to existing legally marketed devices.



AUG 16 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Theken Spine  
% Mr. Dale Davison  
Vice President of Engineering  
283 E. Waterloo Road  
Akron, Ohio 44319

Re: K070638  
Trade/Device Name: Atoll™ Cervico-Thoracic System  
Regulation Number: 888.3050  
Regulation Name: Spinal interlaminar fixation orthosis  
Regulatory Class: II  
Product Code: KWP and MNI  
Dated: March 5, 2007  
Received: March 7, 2007

Dear Mr. Davison:

This letter corrects our substantially equivalent letter of May 30, 2007.

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 (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.

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); good manufacturing practice requirements as set

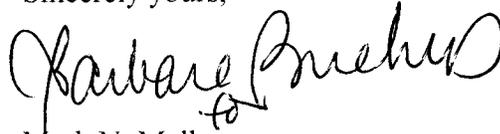
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0120 or view their Internet address <http://www.fda.gov/cdrh/organiz.html#OC> for OC organization structure. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with a small "to" written below the main name.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

## Indications for Use

510(k) Number (if known): K0706838

Device Name: Theken Atoll Cervico-Thoracic System

Indications For Use: The Atoll Cervico-Thoracic System is indicated to promote fusion of the cervico-thoracic regions of the spine (C1-T3). The intended indications are as follows: degenerative disc disease (as identified by neck or back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; spinal stenosis; fracture/dislocation; tumors; pseudoarthrosis; and revision of previous cervical and upper thoracic spine surgery.

The use of the screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. The screws are not intended for use in the cervical spine. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

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

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

**(Division Sign-Off)** Barbara Frueh MD for MAM  
Concurrence of CDRH, Office of Device Evaluation (ODE)  
**Division of General Restorative,  
and Neurological Devices**

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