FEB - 7 2005

K041798

510(k) Summary

Submitted on behalf of:

U.S. Spinal Technologies, Inc.
3600 FAU Blvd. Ste 101
Boca Raton, FL 33431, USA
Telephone: 561-367-7463
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by: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
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CONTACT PERSON: Elaine Duncan

DATE PREPARED: January 27, 2005
TRADE NAME: **Atalia Titanium Surgical Mesh**
COMMON NAME: vertebral body replacement

SUBSTANTIALLY EQUIVALENT TO:
The Atalia Titanium Surgical Mesh is substantially equivalent to various features and performance characteristics to the Osteotech VBR (K003155), the Depuy Acromed Surgical Titanium Mesh (K003043) and the Blackstone Surgical Mesh System (K030744) as detailed in the submission.

DESCRIPTION of the DEVICE:
The Atalia Titanium Surgical Mesh is a round-patterned, surgical mesh device. The body is manufactured from TI-6AL-4V ELI Alloy conforming to ASTM F 136. Because of the construction, the angle and the length of the mesh can be reduced incrementally to adjust it to individually anatomical conditions. The Atalia Surgical Mesh System is sold non-sterile.

INDICATIONS FOR USE:
The Atalia Titanium Surgical Mesh is indicated for use in the thoraco-lumbar spine (T1-L5), in cases where one vertebral body has been structurally compromised either by tumor or trauma. The objective is the restoration of anterior column support through introduction of a corpectomy construct in tandem with bone graft to ultimately realize spinal fusion. The Atalia Titanium Surgical Mesh is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and/or lumbar spine.

SUMMARY of TESTING:
The Atalia Titanium Mesh (U.S. Spinal Technologies) was tested in accordance with ASTM F2077.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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U.S. Spinal Technologies, Inc.
c/o Ms. Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, Minnesota 55082

Re: K041798
Trade/Device Name: Atalia Titanium Surgical Mesh
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 10, 2004
Received: January 21, 2005

Dear Ms. Duncan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 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 begin 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) 276-0115. 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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

PRODUCT NAME: Atalia Titanium Surgical Mesh

510(k) Number (if known): K041798

The Atalia Titanium Surgical Mesh is indicated for use in the thoraco-lumbar spine (T1-L5), in cases where one vertebral body has been structurally compromised either by tumor or trauma. The objective is the restoration of anterior column support through introduction of a corpectomy construct in tandem with bone graft to ultimately realize spinal fusion. The Atalia Titanium Surgical Mesh is intended to be used with supplemental internal spinal fixation systems that are cleared by the FDA for use in the thoracic and/or lumbar spine.

Prescription Use ✓ 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K041798