IX. 510(k) Summary

K 021039
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SUBMITTER:	DePuy AcroMed™, Inc. 325 Paramount Drive Raynham, MA 02767-0350 USA
CONTACT PERSON:	Karen F. Jurczak Phone: (508) 828-3704 Fax: (508) 828-3797
DATE PREPARED:	November 01, 2002
PROPRIETARY NAME:	BowTi Anterior Buttress Staple System
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Intervertebral Body
PREDICATE DEVICE:	MacroPore OS Spinal System (K010911)
INTENDED USE:	The BowTi Anterior Buttress Staple System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.
MATERIALS:	ASTM F-136 Material (Ti-6Al-4V)
PERFORMANCE DATA:	Biomechanical testing, including static and fatigue cantilever beam loading, were conducted.
DEVICE DESCRIPTION:	The BowTi Anterior Buttress Staple System consists of a staple and a screw. The staple is uniquely shaped to conform to the anatomy of the anterior spine. It features two prongs, which engage the vertebral body and prevent rotation, and a screw slot for final fixation. The staples have a 5-degree bend, and are available in two sizes, 20mm and 24mm. The self-tapping cancellous screws have a 6.25mm major diameter and are available in lengths of 20mm, 25mm, and 30mm. Both components of the BowTi Anterior Buttress Staple System are manufactured from titanium alloy and have a smooth anodized finish.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2002

Ms. Karen F. Jurczak
Depuy Acromed™
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K021039
Trade/Device Name: BowTi Anterior Buttress Staple System
Regulation Number: 21 CFR §888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: November 1, 2002
Received: November 4, 2002

Dear Ms. Jurczak;

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.
f/t:MMattera:elh:12/09/02

IV. Indications for Use

510(k) Number (if known): K021039

Device Name: BowTi Anterior Buttress Staple System

Indications For Use:

The BowTi Anterior Buttress Staple System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing applications.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021039