K051044 p 1/2

OCT 7 - 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (21CFR 807.92)

I. **DATE PREPARED:**
October 03, 2005

II. **SUBMITTED BY:**
Altiva Corporation
9800 Southern Pines Blvd.
Suite I
Charlotte, NC 28273

III. **CONTACT PERSON:**
John Kapitan
Director of Regulatory Affairs & Quality Assurance
(704) 409-1754

IV. **DEVICE NAME:**
Trade/Proprietary Name: ArcTec™ Semi-Rigid Plating System

V. **DEVICE CLASSIFICATION NAME:**
Pedicle screw spinal system
21 CFR 888.3070, Class II
MNH, MNI

VI. **PREDICATE DEVICE INFORMATION:**
Simmons Stainless Steel Plating System (K930353)
Ultium Plating System (K962784)
HydraLok System (K051216)
Rogozinski Spinal System (K983899)
Titanium Moss Miami Spinal System (K964024)

VII. **DEVICE DESCRIPTION:**
The ArcTec™ Semi-Rigid Plating System includes plates, bolts, washers and locking nuts in addition to standard surgical instrumentation.

K051644 1/2

The semi-rigid low profile plate has a low stiffness and is easy to contour. The patent pending washer design incorporates a unique polyaxial bandclamp feature that allows unlimited range of placement on the plate and screw angulation of up to 10 degrees in any plane. The system combines the simplicity of a plate with the adaptability of a polyaxial screw connection.

VIII. MATERIALS:

The implant components are manufactured from titanium alloy (Ti-6Al-4V per ASTM F136). The implant components are for single use only.

IX. INDICATION FOR USE:

The ArcTec™ Semi-Rigid Plating System is intended for posterior, noncervical, pedicle fixation in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including degenerative spondylolisthesis with objective evidence of neurological impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the ArcTec™ Semi-Rigid Plating System is intended for skeletally mature patients with severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 and below), with removal of the implants after the attainment of solid fusion.

X. SAFETY INFORMATION:

Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the ArcTec™ Semi-Rigid Plating System. In addition, thorough familiarization with the implants, instrumentation, and surgical technique is essential. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

XI. PERFORMANCE DATA

Mechanical testing in accordance with ASTM F1717 was conducted to evaluate performance as a basis for substantial equivalence.

XII. CONCLUSION

Altiva believes sufficient information is included to reach a determination of substantial equivalence to the predicate devices based on intended use, function, design, material and mechanical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2005

John Kapitan
Director of Regulatory Affairs and Quality
Altiva Corporation
9800 Southern Pine Boulevard, Suite 1
Charlotte, North Carolina 28273

Re: K051044
Trade/Device Name: ArcTec™ Semi-Rigid Plating System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI
Dated: September 9, 2005
Received: September 12, 2005

Dear Mr. Kapitan:

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) 276-0120. 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,
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051044

Device Name: ArcTec™ Semi-Rigid Plating System

Indications for Use:

The ArcTec™ Semi-Rigid Plating System is intended for posterior, noncervical, pedicle fixation in order to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including degenerative spondylolisthesis with objective evidence of neurological impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

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

"Caution: Federal law restricts this device to sale by or on the order of a "physician"

(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 General, Restorative, and Neurological Devices

510(k) Number K051044