Summary Of Safety And Effectiveness:

This safety and effectiveness summary for the Micron Precision Engineering AMT Spinal™ System is provided as required per Section 513(i)(3) of the Food, Drug, and Cosmetic Act.

1. **Submitter:**
   Micron Precision Engineering Inc.
   21051 Superior Street
   Chatsworth, CA 91311

NOV 1 3 2002

2. **Mailing Address:**
   939 Evening Shade Drive
   San Pedro, CA 90731

3. **Contact Person:**
   Mr. Frank E. Bailly
   Official Correspondent
   Telephone: (310) 831-1873
   Fax: (818) 727-9685

4. **Trade Name:** AMT Spinal™ System

   Common Name: Pedicle screw fixation system

   Classification Name: Orthosis, Spondylolisthesis Spinal Fixation (MNH)

   FDA Product Code: MNI
   MNH

5. **Predicate or legally marketed devices which are substantially equivalent:**

   - **Spine System Evolution** – Aesculap
   - **Global Spinal Fixation System** – Forex
   - **Global Spinal Fixation System** – U & I Corporation
   - **Spiral Radius 90D** – Surgical Dynamics
   - **Trinity Polyaxial Screw** – Corin Spinal Systems

There are no significant differences between the Micron Precision Engineering AMT Polyaxial Pedicle Screw and the systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

Mechanical testing shows the biomechanical performance of the subject device to be similar to the performance of previously cleared spinal systems with similar indications. It is substantially equivalent to these other devices in design, function, material and intended use.

6. Description of the device:

The AMT Spinal™ System is designed for use as a construct system and consists of set screws, hex nuts, hooks, rods, screws, and cross link assembly (cross link rod and connecting hook) which can be variously assembled to provide immobilization of the thoracic, lumbar, and lumbosacral spine. The system is composed of the following components: right hand set screw, left hand hex nut, pedicle screw, polyaxial screw, rod, cross link assembly (cross link rod and connecting hook). All components are made from Wrought Titanium 6Al4V ELI Alloy (ASTM F-136).

The components under review are the Polyaxial screws, Polyaxial upper body head, and concave compression washer. The AMT Polyaxial Pedicle Screw serves as an additional option to the pedicle screw configurations currently offered in the AMT Spinal™ System (K002059), in a construct system. The AMT Polyaxial Pedicle Screw utilizes the same straight forward simple instruments and is identical to the pedicle screws currently offered in the AMT Spinal™ System in the all areas with the exception of the following:

The top loading polyaxial head allowing for greater positioning abilities.

- The rotating head (polyaxial) eliminates the need to bend rods for constructs up to the three (3) vertebral levels.
- The rotating head (polyaxial) can be rotated allowing the surgeon greater versatility in positioning rod and screws to the anatomy.
- Allows anatomical screw placement and easy rod positioning.
- This allows the surgeon multi-angle pedicle screw insertion.

Materials: All components are made from Wrought Titanium 6Al4V ELI Alloy (ASTM F-136).

Function: The system functions to assist in arthrodesis or fusion of the thoracic, lumbar and lumbosacral spine.

7. Intended Use:

When used as a pedicle screw fixation system in the non-cervical spine of skeletally mature patients (MNI), The AMT Spinal™ System is intended for immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (1) severe degenerative spondylolithesis with objective evidence of neurological impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and (7) failed previous fusion (pseudoarthrosis).

The AMT Spinal™ System is intended for skeletally mature patients (MNH): (1) having severe spondylolithesis (Grades 3 and 4) at the L5-S1 vertebral joint; (2) who are receiving fusion by autogenous bone graft only; (3) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (4) who are having the device removed after the development of a solid fusion mass.

8. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

There are no significant differences between the AMT Polyaxial Pedicle Screw and the AMT Spinal™ System currently being marketed which would adversely affect the use of the product. It is substantially equivalent to this device in design, function, material and intended use.

Parameter	Identical, Similar, or Different	Similarities and Differences
Design	Identical Different	• Both the predicate and the proposed devices have the same profile and geometry. • The proposed device has a top loading rotating head to allow greater versatility in positioning rod and screws to the anatomy.
Materials	Identical	• Ti-6Al-4V ELI Alloy for both the predicate and the proposed devices.
Manufacturing Process	Identical Identical	• Both the predicate and the proposed devices are machined in the same process. • Both the predicate and the proposed devices are machined using the material specifications.
Biocompatibility	Identical	• The materials used meet or exceed ASTM standards, are common to orthopedic products today, and leave an extensive safe clinical history .
Pyrogenicity	Identical	• Neither the predicate nor the proposed devices are labeled as non-pyrogenic, Per USP XXII, NF18 (1995 edition). "These requirements do not apply to orthopedic products."
Sterility	Identical Identical	• Both the predicate and the proposed devices will be supplied as a non-sterile implant. • Both the predicate and the proposed devices will be steam sterilized.

9. Non-clinical Performance and Conclusions:

The Food and Drug Administration have established no performance standards applicable to pedicle screw systems. However, static and fatigue compression and static torsion testing of the AMT Polyaxial Pedicle Screw were performed according to ASTM F1717-96. Data regarding the functional performance of the proposed AMT Polyaxial Pedicle Screw has been generated.

10. Clinical Performance and Conclusion:

Clinical data and conclusion were not needed for this device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2002

Mr. Frank E. Bailly
Official Correspondent
Micron Precision Engineering, Inc.
939 Evening Shade Drive
San Pedro, California 90731

Re: K022768
Trade Name: AMT Polyaxial Pedicle Screw – AMT Polyaxial Pedicle Screw
Regulation Number: 888.3070
Regulation Names: Pedicle Screw Spinal System and Spondylolisthesis Spinal Fixation Device System
Regulatory Class: II
Product Codes: MNI and MNH
Dated: August 12, 2002
Received: August 21, 2002

Dear Mr. Bailly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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.

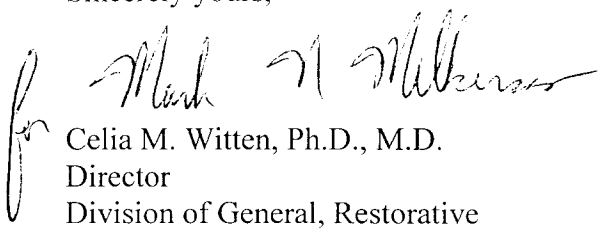
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

510(k) Number (if known): K022768

Device Name: AMT Spinal™ System

Indications for Use

When used as a pedicle screw fixation system in the non-cervical spine of skeletally mature patients (MNI), The AMT Spinal™ System is intended for immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (1) severe degenerative spondylolithesis with objective evidence of neurological impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and (7) failed previous fusion (pseudoarthrosis).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhoan

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

510(k) Number K022768

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)