

APR 14 2000

Summary of Safety and Effectiveness Information	IAME, INC.
Premarket Notification, Section 510(k) K993503	SEPTEMBER 1999

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

HAIDER-UCR Spinal System

Common Name(s):

Pedicle screw spine system

Classification Name(s):

Pedicle Screw Spinal System

2. Establishment Information:

Name: INTERNATIONAL ADVANCED MEDICAL ENTERPRISES, INC.
Number: 9033791
Address: 5360 Preserve Parkway, S
909.682.9616 - 909.682.9620 - fax
Greenwood Village, CO 80121

3. Classification:

§ 888.3070 – Spondylolisthesis Spinal Fixation Device System
§ 888.3070 – Pedicle Screw Spinal System (Class II Uses)

Device Class: Class II for the requested indications
Classification Panel: Orthopaedic and Rehabilitation Devices Panel
Product Code(s): MNH, MNI respectively

4. Equivalent Predicate Device:

Synergy™ Spinal System: K974749, Cross Medical Products, Inc. (now Interpore Cross International).

5. Device Description:

Indications for Use: when used as a **Spondylolisthesis Spinal Fixation Device System**, 87MNH the intended use and indications for use are:

The *HAIDER-UCR Spinal System* is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

When used as a **Pedicle Screw Spinal System**, (Class II uses) **87MNI** the intended use and indications for use are:

The *HAIDER-UCR Spinal System* is a pedicle screw system intended 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:

- degenerative spondylolisthesis with objective evidence of neurological impairment,
- fracture,
- dislocation,
- scoliosis,
- kyphosis,
- spinal tumor, and
- failed previous fusion pseudarthrosis).

The system components include:

Component	Catalog Number	Level of Use
Titanium Pedicle screw		
7.0mm dia., Assembled		
7.0mm X 35mm	40-35	T-10 to Sacrum
7.0mm X 40mm	40-40	T-10 to Sacrum
7.0mm X 45 mm	40-45	T-10 to Sacrum
Pedicle Screw Components		
Set Screw	60-10	T-10 to Sacrum
Washer	60-15	T-10 to Sacrum
Cap	60-20	T-10 to Sacrum
Housing	60-25	T-10 to Sacrum
Screw Sub-Assembly		
7.0mm X 35mm	60-35	T-10 to Sacrum
7.0mm X 40mm	60-40	T-10 to Sacrum
7.0mm X 45 mm	60-45	T-10 to Sacrum
Crosslink		
Cross Link Nut	50	L-1 to L-5
Cross Link Hook	55	L-1 to L-5
Cross-link Bar-60mm	70-60	L-1 to L-5
Cross-link Bar-70mm	70-70	L-1 to L-5
Cross-link Bar-80mm	70-80	L-1 to L-5
5.5 mm Titanium Rods		
5.5mm X 305mm	95	T-10 to Sacrum
Accessories		
Hex 3mm Screw Driver	300	
Hex 4mm Screw Driver	400	

Materials: The system is made from a well known metallic alloy commonly known as titanium alloy or 6Al, 4V, Ti titanium alloy. This material meets or exceeds the quality and composition standards listed in the table below:

6AL4VTI	ASTM F136-92	ISO 5832-3
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Testing Summary: Static and fatigue testing were conducted. Static tests of compression bending, tension bending and torsion of a typical system configuration indicated design performance was met. All samples were tested according to ASTM F-1717-96, the pedicle screw spinal system guideline. Samples subjected to cyclic fatigue testing also performed according to expectations. Seven constructs were tested and an S/N curve established. At least two run out points exceeded 5,000,000 load cycles.

7. Company Contact:

Todd L. Ackarman
Regulatory Affairs
IAME, INC.

8. Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

9. Performance Standards:

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9000 series quality regulations.

IAME, INC. also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. Special Controls:

Special controls were published in the Federal Register, Vol. 63, No. 143, July 27, 1998 (Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems). The following special controls apply to the marketing of this device when used as a posterior pedicle system:

- (i) Compliance with material standards,
- (ii) Compliance with mechanical testing standard,
- (iii) Compliance with biocompatibility standard, and
- (iv) Compliance with specified labeling requirements.

11. Storage, Packaging & Sterilization Information:

The *HAIDER-UCR Spinal System* is supplied "**NON-STERILE**" and must be sterilized prior to use.

The recommended sterilization process is high temperature steam autoclave sterilization. The recommended sterilization cycle will produce a Sterility Assurance Level (SAL) of at least 10^{-6} .

The validated cycle is:

Method: Steam
Cycle: Gravity
Temperature: 270°F (125°C)
Exposure Time: 15 minutes

All packages containing implants or instruments should be intact upon receipt. If the package or product is damaged, the product should not be used and should be returned. Product must be handled, stored and opened in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following cleaning, sterilization and accepted surgical sterile technique.

12. Summary Comparison Table:

FEATURE	<i>HAIDER-UCR Spinal System</i>	<i>Synergy™ Spinal System</i>	SE?
Indications for Use:	degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion pseudarthrosis).	SAME	YES
Materials:	Titanium alloy	SAME	YES
Design:	Rod, sacral screw, pedicle screw & cross link system	SAME	YES
Sterile:	Supplied Non-sterile Autoclave processed by end user	SAME	YES
Sizes:	Rods: 5.5mm dia. X 40-305mm length Pedicular screws 7.0mm 35mm, 40mm, 45mm	EQUIVALENT	YES
Manufacturer:	IAME, Inc.	Interpore/Cross	YES
Product Code:	MNH, MNI	SAME	YES
K - Number:	Pending	K974749	YES

**APR 14 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David W. Schlerf
Buckman Company, Inc.
c/o IAME, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K993503
Trade Name: HAIDER-UCR Spinal System
Regulatory Class: II
Product Code: MNH and MNI
Dated: January 10, 2000
Received: February 24, 2000

Dear Mr. Schlerf:

We have reviewed your Section 510(k) 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 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

Page 2 - Mr. David W. Schlerf

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Celia M. Witten

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

Enclosure

510(k) Number : K993503

Device Name(s): *HAIDER-UCR Spinal System*

Intended Use Statement(s):

1. Spondylolisthesis Spinal Fixation Device System, 87MNH the intended use and indications for use are:

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 - spinal tumor, and
 - failed previous fusion pseudarthrosis).

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna D. Lochner
 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K993503

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____
(Optional format 1-2-96)