

DEC 17 1999

Summary of Safety and Effectiveness Information	ORTHOtec, LLC.
Premarket Notification, Section 510(k)	NOVEMBER 1999

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

1. Device Name:

Trade Name: **OmniAxial Connector (SCS Spinal System)**
Common Name(s): pedicle screw spine system
Classification Name(s): Pedicle Screw Spinal System (Class II Uses)

2. Establishment Name & Registration Number:

Name: **ORTHOtec, LLC.**
Number: 2031734

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): KWP KWQ & MNH, MNI

4. Equivalent Predicate Device:

The **OmniAxial Connector** may be directly contrasted with the earlier screw-rod connector of the **SCS Spinal System, K983353**. The **OmniAxial Connector** performs essentially the same function as the original connector. The basic design, dimensional tolerances, materials and intended use of both devices are identical.

5. Device Description:

This new connector is called the "Omni Axial Connector." The part number is **7T20-C004**. It is made from titanium alloy as defined by the ASTM and ISO standards indicated below.

TA6V ELI	ASTM F136-92	ISO 5832-3
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The **OmniAxial Connector** facilitates pedicle screw insertion by providing a range of adaptability of the screw path in the three axis: axial, sagittal and coronal. The **OmniAxial Connector** is intended to be a "standard" component of the **SCS Spinal System**. The **OmniAxial Connector** attaches to the spinal rods using the same connecting screw (2T01-VS53) as used in the existing **SCS Spinal System**.

Summary of the Testing:

Mechanical and fatigue testing were carried out. Samples were tested using the ASTM F-1717-96 guidance document. The maximum and minimum loads, positions and temperatures were recorded. Static testing sufficient to quantify and compare the previously cleared **SCS Spinal System** connector and the new **OmniAxial Connector** clearly demonstrates the substantial equivalence of the two connectors. The product is manufactured in compliance with cGMP regulations.

6. Applicant Name & Address:

ORTHOtec, LLC.
546 Hillgreen Drive
Beverly Hills, CA 90212-4110
310.557.2000 ~ 310.843.9500 – fax

7. **Company Contact:**
Regulatory Affairs
*ORTHO*TEC, LLC.
546 Hillgreen Drive
Beverly Hills, CA 90212-4110
310.557.2000 ~ 310.843.9500 - fax
8. **Submission Correspondent:**
Mr. David W. Schlerf
Buckman Company, LLC.
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. *ORTHO*TEC, LLC. In addition, 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. **Special Guidance Document Information:**
The 510(k) was prepared in accordance with:
- "Guidance for Spinal System 510(k)'s," May 7, 1999.
 - "The New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance, March 20, 1998.
12. **Storage, Packaging & Sterilization Information:**
The *Omniaxial Connector* is supplied "**NON-STERILE**" and must be sterilized before 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: 250°F (121°C)
Exposure Time: 30 minutes
- All packages containing implants or instruments should be intact upon receipt. Damaged packaging may indicate the presence of unsafe product. 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.

13. Summary Comparison Table:

FEATURE	SCS Spinal System <i>OmniAxial Connector</i>	SCS Spinal System	SE?
Indications for Use:	<p>As a Non-pedicle posterior system: spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, pseudarthrosis, failed previous fusion (pseudarthrosis).</p> <p>As a Anterolateral/anterior system: spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, pseudarthrosis, failed previous fusion (pseudarthrosis).</p> <p>As a Posterior pedicle system: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis spinal tumor, failed previous fusion (pseudarthrosis), severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint, Fusions using autogenous bone graft only, Device fixed or attached to the lumbar and sacral spine, device removed after the development of a solid fusion mass.</p>	SAME	YES
Design:	OmniAxial pedicle screw	SAME	YES
Sterile:	Non-sterile	SAME	YES
Sizes:	OmniAxial Pedicle Screws: 6-7mm dia. X 30-55mm length	EQUIVALENT	YES
Material:	Stainless steel, titanium alloy, pure titanium	SAME	YES
Manufacturer:	OrthoTec, LLC.	OrthoTec, LLC.	YES
Product Code:	KWP KWQ & MNH	SAME	YES
K - Number:	K993926	K983353	YES

14. Intended Use:

When used as a nonpedicle posterior system, the SCS system is indicated for patients with:

- degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- spondylolisthesis
- fracture
- spinal stenosis
- deformities (i.e., scoliosis, kyphosis, lordosis)
- tumors
- pseudarthrosis
- failed previous fusion (pseudarthrosis)

When used as an anterolateral/anterior system the SCS system is indicated for patients with:

- degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- spondylolisthesis
- fracture
- spinal stenosis
- deformities (i.e., scoliosis, kyphosis, lordosis)
- tumors
- pseudarthrosis
- failed previous fusion (pseudarthrosis)

When used as a posterior pedicle system, the device is indicated for use in skeletally mature patients L3 & below who are:

- having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint
- receiving fusions using autogenous bone graft only
- having the device fixed or attached to the lumbar and sacral spine
- having the device removed after the development of a solid fusion mass.

Posterior pedicle systems are 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 neurologic impairment
- fracture
- dislocation
- scoliosis
- kyphosis
- spinal tumor
- failed previous fusion (pseudarthrosis)



DEC 17 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993926
Trade Name: SCS Spinal System
Regulatory Class: II
Product Code: MNH, KWQ, KWP, and MNI
Dated: October 11, 1999
Received: November 18, 1999

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 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 (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.

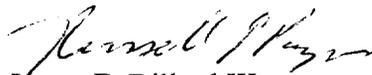
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (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,



for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K993926

Device Name(s): *Omni-axial Connector (SCS Spinal System)*

Intended Use(s) of the Device:

When used as a nonpedicle posterior system, the SCS system is indicated for patients with:

- degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- spondylolisthesis
- fracture
- spinal stenosis
- deformities (i.e., scoliosis, kyphosis, lordosis)
- tumors
- pseudarthrosis
- failed previous fusion (pseudarthrosis)

When used as an anterolateral/anterior system the SCS system is indicated for patients with:

- degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- spondylolisthesis
- fracture
- spinal stenosis
- deformities (i.e., scoliosis, kyphosis, lordosis)
- tumors
- pseudarthrosis
- failed previous fusion (pseudarthrosis)

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- degenerative spondylolisthesis with objective evidence of neurologic impairment
- fracture
- dislocation
- scoliosis
- kyphosis
- spinal tumor
- failed previous fusion (pseudarthrosis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K993926

Prescription Use X
(Per 21 CFR 801.109)

OR

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