K994288
1 of 3

APR 1 0 2000

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

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

1. **Device Name:**
   Trade Name: 5.0mm Spinal Screw (***SCS Spinal System***)
   Common Name(s): pedicle screw
   Classification Name(s): Pedicle Screw Spinal System (Class II Uses)

2. **Establishment Name & Registration Number:**
   Name: ORTHOTEC, LLC.
   Number: 2031734

3. **Classification:**
   § 888.3050 – Spinal Interlaminal Fixation Orthosis
   § 888.3060 – Spinal Intervertebral Body Fixation Orthosis
   § 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, respectively

4. **Equivalent Predicate Device:**
   The ***5.0mm Spinal Screws*** may be directly contrasted with the larger diameter cleared spinal screws of *SCS Spinal System, K983353*. Other than the reduced major screw diameter, the ***5.0mm Spinal Screws*** are essentially the same as the cleared spinal screws in the existing *SCS Spinal System*. The basic design, dimensional tolerances, materials and intended use are identical.

5. **Device Description:**
   The ***5.0mm Spinal Screws*** . The new diameter screws are made of titanium and stainless steel per the referenced specifications

316LVM	ASTM F138 GR2	ISO 5832-1
TA6V ELI	ASTM F136-92	ISO 5832-3

The product is manufactured in the same facility as the other components of the *SCS Spinal System* following identical manufacturing procedures in full compliance with cGMP regulations.

The ***5.0mm Spinal Screws*** facilitates screw insertion by providing an alternative to the larger 6, 6.5 or 7.0mm pedicle screws or vertebral screws available in the cleared system. This new screw diameter allows the surgeon to insert screws in cases where the spine deformity or the small size of the pedicle would not permit insertion of larger diameterscrews. The smaller diameter of the ***5.0mm Spinal Screws*** permits the surgeon to address the needs of a larger patient population.

The ***5.0mm Spinal Screws*** are to be a new "standard" screw for the *SCS Spinal System* with an identical coding for product reference in which "xx" represents the length of the screw, 2010, represents the reference for stainless steel products and 2T10 represents the reference for titanium products.

Screw Type	Stainless Steel	Titanium
R	2010-R5xx	2T10-R5xx
V	2010-V5xx	2T10-V5xx
L	2010-L5xx	2T10-L5xx
S	2010-S5xx	2T10-S5xx
U	2010-U5xx	2T10-U5xx
H	2010-H5xx	2T10-H5xx

The new screw will be used in all *SCS Spinal System* applications where a smaller screw would be of benefit. Therefore, the mechanical characteristics of mechanical and fatigue performance are important. The balance of the *SCS Spinal System* components will remain the same. Other than the major and minor diameter of the cancellous threads the new 5.0mm screws are identical to the existing screws. Rod attachment method and the use of all couplers are the same as were previously cleared for commercialization. Materials are identical

Testing Summary:
Mechanical and fatigue testing were carried out. Samples were tested using the ASTM F-1717-96 guidance document. Tests were performed with an Instron 8500 digital Materials Test System. The maximum and minimum loads, positions and temperatures were recorded. Static testing sufficient to quantify and compare the other previously cleared screw of the *SCS Spinal System* are complete. Testing was conducted to run-out points of 5,000,000 cycles. Results indicate suitability and equivalence of the new screws versus the existing larger diameter screws.

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
ORTHOTEC, 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. *ORTHOTEC, 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 biocompatability 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

13. Summary Comparison Table:

FEATURE	*SCS Spinal System* ***OmniAxial Connector***	*SCS Spinal System*	SE?
Indications for Use:	**As a Non-pedicle posterior system:** spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, pseudarthrosis, failed previous fusion (pseudarthrosis). ***As a Anterolateral/anterior system:*** *spondylolisthesis, fracture, spinal* stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, pseudarthrosis, failed previous fusion (pseudarthrosis). **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.	SAME	YES
Design:	Omniaxial pedicle screw	SAME	YES
Sterile:	*Non-sterile*	SAME	YES
Sizes:	5.0mm	6-7mm dia	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:	*pending*	K983353	YES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2000

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

Re: K994288
Trade Name: SCS Spinal System
Regulatory Class: II
Product Code: MNH, KWQ, KWP, and MNI
Dated: March 15, 2000
Received: March 22, 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 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.

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,

Donna R Lechner.

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: K994088

Device Name(s): ***5.0mm Spinal Screws*** *(SCS Spinal System)*

Intended Use(s) of the Device:

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

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

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

1. degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
2. spondylolisthesis
3. fracture
4. spinal stenosis
5. deformities (i.e., scoliosis, kyphosis, lordosis)
6. tumors
7. pseudarthrosis
8. 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:

1. having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint
2. receiving fusions using autogenous bone graft only
3. having the device fixed or attached to the lumbar and sacral spine
4. 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:

1. degenerative spondylolisthesis with objective evidence of neurologic impairment
2. fracture
3. dislocation
4. scoliosis
5. kyphosis
6. spinal tumor
7. failed previous fusion (pseudarthrosis)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994088

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