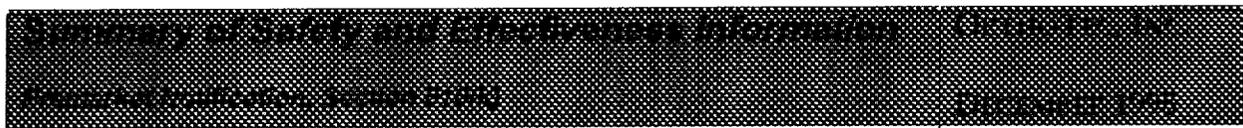


DEC 18 1998

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

1. **Device Name:**

Trade Name: *SCS Spinal System*

Common

Name(s): Anterior spine system, posterior spine system, pedicle screw spine system, hook and rod spine system

Classification

Name(s):

1. Spinal Interlaminar Fixation Orthosis
2. Spinal Intervertebral Body Fixation Orthosis
3. Pedicle Screw Spinal System

2. **Establishment Name & Registration Number:**

Name: ORTHOTEC, INC.

Number: Pending

3. **Classification:**

§ 888.3050 – Spinal Interlaminar Fixation Orthosis

(a) Identification. A spinal interlaminar fixation orthosis is a device intended to be implanted made of an alloy, such as stainless steel, that consists of various hooks and a posteriorly placed compression or distraction rod. The device is implanted, usually across three adjacent vertebrae, to straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together. The device is used primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also may be used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.

(b) Classification. Class II.

§ 888.3060 – Spinal Intervertebral Body Fixation Orthosis

(a) Identification. A spinal intervertebral body fixation orthosis is a device intended to be implanted made of titanium. It consists of various vertebral plates that are punched into each of a series of vertebral bodies. An eye-type screw is inserted in a hole in the center of each of the plates. A braided cable is threaded through each eye-type screw. The cable is tightened with a tension device and it is fastened or crimped at each eye-type screw. The device is used to apply force to a series of vertebrae to correct sway back, scoliosis (lateral curvature of the spine), or other conditions.

(b) Classification. Class II.

K983353
a & 5**§ 888.3070 – Pedicle Screw Spinal System**

(a) Pedicle screw spinal systems—(1) Identification. Pedicle screw spinal systems are multiple component devices, made of a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium, that allows the surgeon to build an implant system to fit the patients anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors. The devices 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 or 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, and failed previous fusion (pseudoarthrosis). (2) Classification. Class II (special controls). Pedicle screw spinal systems must comply with the following special controls:

- (i) Compliance with material standards,
- (ii) Compliance with mechanical testing standard,
- (iii) Compliance with biocompatibility standard, and
- (iv) Labeling which contains the following statements in addition to other appropriate labeling information.

“Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.”

“Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.”

(b) Pedicle screw spinal systems for all other uses (1) Identification. Pedicle screw spinal systems for all other uses are multiple component devices, made from a variety of materials, including alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, Ti-6Al-4V, and unalloyed titanium, that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.

(2) Classification. Class III (premarket approval)

(c) Date PMA or notice of completion of a PDP is required. An approved PMA or a declared completed PDP must be in effect before placing the device in commercial distribution. See Sec. 888.3.

Device Class: Class II

Classification Panel: Orthopaedic and Rehabilitation Devices Panel

Product Code(s): KWP KWQ & MNH respectively

K983353
3 of 5**4. Equivalent Predicate Device:****Synergy™ Spinal System: K974749, K950709 & K950099** – Cross Medical Products, Inc.

The **Synergy™ Spinal System** is cleared for marketing as a system described in all of the following device classifications:

Spinal Interlaminar Fixation Orthosis
 Spinal Intervertebral Body Fixation Orthosis
 Pedicle Screw Spinal System

5. Device Description:

General system description. The *SCS Spinal System* includes implantable components which fit together to form a construct for use during spinal fusion surgery. The system contains components of various designs and sizes that allow the surgeon to build an implant system for each of three defined intended uses and to fit the patient's anatomical and physiological requirements.

Materials. Materials for components of the *SCS Spinal System* are implant grade materials of titanium or stainless steel. The materials comply with applicable standards shown below:

| Titanium Alloy | ASTM F136-92 | ISO 5832-3 |
|----------------|-----------------|------------|
| Titanium | ASTM F67 GR2-95 | ISO 5832-2 |
| 316LVM | ASTM F138 GR2 | ISO 5832-1 |
| | | |

The system components include:

Lumbar, thoracic, and pedicular hooks
 Vertebral screws, open vertebral screws, set screws, sacral screws, and pedicle screws (including self-locking)
 Rods in various lengths
 Connectors with set screws (sacral, anterior, transverse, lateral)
 Connecting elements (longitudinal connectors)
 Instruments
 Sterilizer trays

Testing Summary. Fatigue testing of a typical system configuration was conducted on samples of both stainless steel and titanium. Samples were tested using ASTM F-1717 as a guideline. Samples were tested for each load configuration. At least two run out points exceeded 5,000,000 cycles for each material.

6. Applicant Name & Address:

ORTHOTEC, INC.
 1284 Hillgreen Drive
 Los Angeles, CA 90035-1021
 310.557.2000 ~ 310.843.9500 – fax

7. Company Contact:

Regulatory Affairs
 ORTHOTEC, INC.
 1284 Hillgreen Drive
 Los Angeles, CA 90035-1021
 310.557.2000 ~ 310.843.9500 - fax

K983353
4 of 5**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. **ORTHOtec, 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 **SCS 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: 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.

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12. Summary Comparison Table:

| FEATURE | SCS Spinal System | Synergy™ 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: | Hook, rod, vertebral screw, sacral screw, pedicle screw & cross link system | SAME | YES |
| Sterile: | Non-sterile | SAME | YES |
| Sizes: | Rods: 5.8-6.0mm dia. X 40-540mm length | EQUIVALENT | YES |
| Material: | <p>Hooks: Small, Medium, Large, Offset, Pedicular, Transverse, Thoracic</p> <p>Vertebral Screws: 5-10mm dia. X 35-50mm length</p> <p>Sacral Screws: 6-7mm dia. X 30-55mm length</p> <p>Stainless steel, titanium alloy, pure titanium</p> | SAME | YES |
| Origin: | EUROPEAN | USA | YES |
| Manufacturer: | OrthoTec, Inc. | CROSS MEDICAL | YES |
| Product Code: | KWP KWQ & MNH | SAME | YES |
| K-Number: | Pending | K974749, K950709 & K950099 | YES |

13. 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)
 The system is indicated for thoracic, lumbar and sacral level.

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)
 The system is indicated for thoracic and lumbar level.

When used as a posterior pedicle system, the device is indicated for use in skeletally mature patients 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.
 Screw fixation is limited to L3 and below.

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 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983353
Trade Name: SCS Spinal System
Regulatory Class: II
Product Codes: MNI, MNH, KWQ, and KWP
Dated: September 21, 1998
Received: September 23, 1998

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.

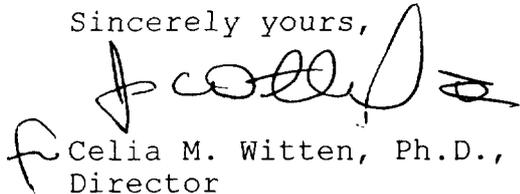
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Mr. David W. Schlerf

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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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 : K983353

Device Name(s): *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)

The system is indicated for thoracic, lumbar and sacral level.

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)

The system is indicated for thoracic and lumbar level.

When used as a posterior pedicle system, the device is indicated for use in skeletally mature patients 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.

Screw fixation is limited to L3 and below.

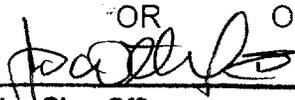
Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

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

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

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



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983353