

K971289

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VIII. 510(k) Summary of Safety and Effectiveness

JUN 18 1997

1. Submission Applicant & Correspondent:

Name: Osteotech, Inc.
 Address: 51 James Way
 Eatontown, NJ 07724
 Phone No.: (908) 542-2800
 Contact Person: Christopher Talbot
 Date of Summary: April 4, 1997

2. Name of Device:

Trade/Proprietary/Model Name: SSCS (Segmental Spinal Correction System) - Addition of Hinged Screw Component
 Common or Usual Name: Posterior Spinal Fixation Device
 Classification Name: Spinal Interlaminar Fixation Orthosis; Spondylolisthesis Spinal Fixation Device System

3. Devices to Which New Device is Substantially Equivalent:

| <u>Trade/Proprietary/Model Name</u> | <u>Manufacturer</u> |
|-------------------------------------|---------------------|
| SSCS (K955173) | Heinrich C. Ulrich |
| ISOLA | Acromed |
| TSRH | Sofamor-Danek |
| CD (Cotrel-Dubousset) | Sofamor-Danek |

4. Device Description:

The SSCS (Segmental Spinal Correction System) is a spinal fixation system comprised of various types and sizes of components, including the SSCS Hinged Screw, that are implanted via a posterior surgical approach and assembled to create a spinal construct. The SSCS also includes instrumentation/accessories that aid in assembling and/or implanting the components.

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Like most other posterior spinal fixation systems, the SSCS is comprised basically of 1) bone screws for attachment of the device to the spine, 2) longitudinal rods which are attached to the bone screws and which transmit loads across the pathologic segments of the spine, and 3) optional transverse connecting elements which link the two longitudinal rods for added construct stability.

5. Intended Use/Indications

The Segmental Spinal Correction System (SSCS), including the SSCS Hinged Screw, is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies in the thoraco-lumbo-sacral portion of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the SSCS are dependent in part on the configuration of the assembled device as described below.

When used as a thoracic/lumbar hook or sacral screw and hook system, the SSCS is intended for instrumentation of the spine at levels ranging from T1 to S2 and is indicated for:

- scoliosis
- kyphosis
- spinal fractures
- degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- tumors
- stenosis
- spondylolisthesis
- pseudoarthrosis
- previously failed attempts at spinal fusion

When used as a sacral/pedicle screw system, the SSCS is intended for patients:

1. Having severe spondylolisthesis (grade 3 or 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint
2. Who are receiving fusions using autogenous bone graft only.
3. Who are having the device fixed or attached to the lumbar and sacral spine.
4. Who are having the device removed after the development of a solid fusion mass.

Although the levels of fusion may not go above the L5-S1 joint, the SSCS screws may be inserted into pedicles up to, but not above, L-3.

6. Technical Comparison

The SSCS, with the addition of the Hinged Screws, is similar to the previously cleared SSCS that included Rigid Screws (K955173) and to other predicate devices in terms of its design, technical characteristics, and materials. These devices consist of several basic types and various sizes of implantable components including longitudinal rods, bone screws, and transverse connectors that are assembled to create a spinal construct.

The SSCS Hinged Screws, like the SSCS Rigid Screws and the bone screws of other predicate spinal systems serve as anchoring elements to attach the device to the spine. In all of these devices, bilaterally placed rods, the longitudinal elements of the spinal system constructs, are attached to the heads of the implanted screws.

The SSCS Hinged Screw shares many of the same design, dimensional and material characteristics as the SSCS Rigid Screw and employs the same interconnection mechanism for attachment of the screw to the rod. The distinguishing feature of the SSCS Hinged Screw compared to the SSCS Rigid Screw is the existence of a hinged connection between the screw head and shaft, as opposed to the Rigid Screw in which the head and shaft are solidly joined.

7. Performance Data

Mechanical testing of SSCS Hinged Screw constructs was performed in accordance with the ASTM Provisional Standard for testing spinal implant devices. The results of this testing demonstrated that the mechanical performance characteristics (bending-compression static strength and stiffness, torsional stiffness and fatigue strength) of SSCS Hinged Screw constructs are at least comparable to, if not better than, those of SSCS Rigid Screw constructs and/or other predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Christopher W. Talbot
Manager of Regulatory Affairs
Osteotech Inc.
51 James Way
Eatontown, New Jersey 07724

JUN 18 1997

Re: K971289
SSCS Hinged Screws to be used with the
Segmental Spinal Correction System
Regulatory Class: II
Product Codes: MNH and KWP
Dated: April 4, 1997
Received: April 7, 1997

Dear Mr. Talbot:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal, Food, Drug, and Cosmetic Act (Act). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.
2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

WARNINGS:

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.

- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:

device component fracture,
loss of fixation,
non-union,
fracture of the vertebra,
neurological injury, and
vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.
4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or those of other manufacturers, may also be required.

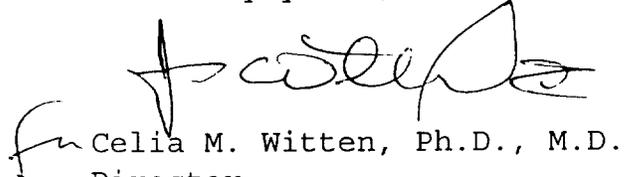
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the 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

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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,



fu 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

I. Indications for Use Statement

510(k) Number (if known): K971289
Device Name: SSCS (Segmental Spinal Correction System)

Indications For Use:

The SSCS is intended for use as a posterior spinal fixation device, with specific indications as follows:

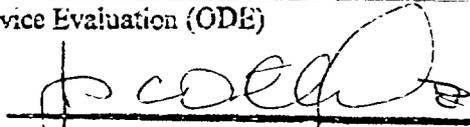
- 1) When used as a thoracic/lumbar hook or sacral screw and hook system, the SSCS is intended for instrumentation of the spine at levels ranging from T1 to S2 and is indicated for:
 - scoliosis
 - kyphosis
 - spinal fractures
 - degenerative disc disease, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
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- 2) When used as a sacral/pedicle screw system, the SSCS is intended for patients:
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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)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K971289

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)