JUL 23 1999

K991586

VIII. 510(k) Summary of Safety and Effectiveness

1. Submission Applicant & Correspondent:

| | |
|---|---|
| Name: | Osteotech, Inc. |
| Address: | 51 James Way<br>Eatontown, NJ 07724 |
| Phone No.: | (732) 542-2800 |
| Contact Person: | Christopher Talbot |
| Date of Summary: | May 6, 1999 |

2. Name of Device:

| | |
|---|---|
| Trade/Proprietary/Model Name: | SSCS (Segmental Spinal Correction System) |
| Common or Usual Name: | Posterior Spinal Fixation Device |
| Classification Name: | Spinal Interlaminal Fixation Orthosis; Spondylolisthesis Spinal Fixation Device System; Pedicle Screw Fixation System |

3. Devices to Which New Device is Substantially Equivalent:

The SSCS is substantially equivalent, for the purpose of this 510(k) adding indications, to the following predicate devices.

| Trade/Proprietary/Model Name | Manufacturer |
|---|---|
| SSCS | Heinrich C. Ulrich |
| ISOLA | AcroMed |
| TSRH | Sofamor-Danek |

4. Device Description:

The SSCS (Segmental Spinal Correction System) is a spinal fixation system comprised of various types and sizes of components, that are implanted via a posterior surgical approach and assembled to create a spinal construct. Like most other posterior spinal fixation systems, the SSCS is comprised basically of 1) bone screws and hooks for attachment of the device to the spine, 2) longitudinal rods that are attached to the bone screws and hooks either directly or indirectly by means of lateral connectors, and that transmit loads across the pathologic

segments of the spine, and 3) optional transverse connecting elements that link the two longitudinal rods for added construct stability.

5. Intended Use/Indications

The Segmental Spinal Correction System (SSCS) is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies in the thoracic-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 pedicle screw system in the thoracolumbosacral region of the spine, the SSCS is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, when used as a 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 (level of attachment: L3 and below).
4. Who are having the device removed after the development of a solid fusion mass.

6. Performance Data

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1999

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

Re: K991586
Trade Name: Segmental Spinal Correction System
Regulatory Class: II
Product Code: KWP, MNI and MNH
Dated: May 6, 1999
Received: May 7, 1999

Dear Mr. Talbot:

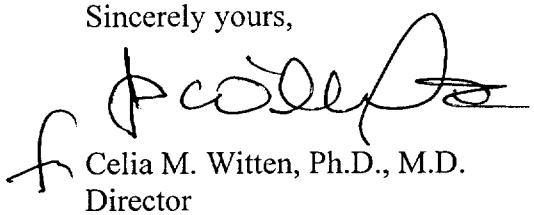
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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): K991586
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); tumors; stenosis; spondylolisthesis; pseudoarthrosis; and previously failed attempts at spinal fusion.

2) When used as a pedicle screw system in the thoraco-lumbo-sacral region of the spine, the SSCS is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

3) In addition, when used as a pedicle screw system, the SSCS is intended for patients:
   a. Having severe spondylolisthesis (grade 3 or 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 (level of attachment: L3 and below).
   d. Who are having the device removed after the development of a solid fusion mass.

(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 K991586

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