



OHIO
MEDICAL
INSTRUMENT
COMPANY INC. CINCINNATI, OHIO 45227

NOV 19 1998

K983282

II. 510(k) SUMMARY AND CERTIFICATION

Summary of Safety and Effectiveness: OMI® Occipital Cervical Loop

Pursuant to Section 513(i) of the Federal Food, Drug and Cosmetic Act, as amended by the Safe Medical Devices Act [SMDA] of 1990.

Summary Preparation Date: November 4, 1998

1. General Information:

Classification Name: Appliance, Fixation, Spinal Interlaminar
Common/Usual Name: Cervical spinal implant
Proprietary Name: OMI® Occipital Cervical Loop

Applicant's/Submitter's Name and Address & Registration Number:

Ohio Medical Instrument Company, Inc. (OMI)
4900 Charlemar Drive
Cincinnati, Ohio 45227

Registration Number: 1525725
Contact Name: Kenneth B. Miller
Contact Title: Regulatory Affairs/Quality Assurance Director
Contact Phone Number: (513) 561-2705
Contact Fax Number: (513) 561-0195

2. Name of predicate device(s):

Ransford Cervical Fixation System™

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.

II. 510(k) SUMMARY AND CERTIFICATION - continued

4. Performance Standards:

No applicable performance standards have been established by FDA under section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description:

Intended Use:

To assist stabilization and fusion of the cervical spine and cervical occipital junction.

Indications for Use:

1. Degenerative disk disease of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiological studies),
2. Spondylolisthesis of the cervical vertebrae,
3. Spinal stenosis of the cervical vertebrae,
4. Atlanto/axial fracture with instability,
5. Cervical-occipital dislocation,
6. Revision of previous cervical fusion surgery,
7. Tumors.

Device Description:

The OMI® Occipital Cervical Loop, Catalog Number A-1089, consists of the following components: Cervical Support Loop
Cross Link,
Compression Blocks (2),
Cervical Support Nuts (2),
and an implantation instrument, the Cervical Support Wrench [11mm].

The OMI® Occipital Cervical Loop is a single-use, permanent device used to assist in stabilization and fusion of the occipital cervical region of the spine. It consists of the Cervical Support Loop [CSL], a contoured rod made of biocompatible titanium having an alloy composition of 6AL-4V ELI, according to ASTM-F136. The CSL is U-shaped, with a circular loop at one end and two free lengths extending lengthwise, parallel to each other, from the loop end. The profile of the CSL resembles that of a normal cervical lordosis from the cervical region of the spine to the occiput of the skull. The Cross Link can be attached to the free end lengths of the CSL for additional rigidity. The Cross Link is flat, with a slot at each end, and can be attached to the CSL with the Compression Blocks and Cervical Support Nuts. The Cross Link, Compression Blocks, and Cervical Support Nuts are also made from 6AL-4V ELI titanium.

These titanium alloy implants are designed for use with multi-filament braided titanium alloy [6Al, 4V] cable, .045 inch [1.1 mm] diameter, 19 inches in length, with a pure, soft titanium mono-filament lead wire 3 inches in length. This wire is Sofamor Danek Catalog # 826-360, the same type of wire cleared for use with Sofamor/Danek spinal devices.

II. 510(k) SUMMARY AND CERTIFICATION - continued

6. Summary of Substantial Equivalence:

The OMI® Occipital Cervical Loop is substantially equivalent to the following device:

- The Ransford Cervical Fixation System™, K965221.

Indications:

- The indications for the OMI® Occipital Cervical Loop are identical to the indications for the predicate device, the Ransford Cervical Fixation System™, currently marketed by Surgicraft, Ltd.

Design:

- Both the OMI® Occipital Cervical Loop and the Ransford Cervical Fixation System™ are posterior attachment surgical approach systems.
- Both systems may be used to treat the same medical or surgical conditions of the cervical spine.
- Both systems have essentially the same cautions and contraindications for use.
- Both are basic spinal rod, crosslink and sublaminar wiring systems.
- Both systems may be attached to the occiput via burr holes and wires.

The concept of sublaminar wires and contoured rods placed posteriorly has been in common use for over 35 years. Most orthopedic and neurosurgery physicians are extensively experienced in these techniques and may be expected to adapt readily to the OMI® Occipital Cervical Loop.

Materials:

- Both the OMI® Occipital Cervical Loop and the predicate device utilize similar titanium implant materials that meet the various BS, ISO and ASTM standards.

Performance:

- Results of comparison static testing and fatigue testing demonstrate that the OMI® Occipital Cervical Loop performs substantially the same as the predicate device. Five (5) static tests and six (6) fatigue tests were run of each of the OMI® Occipital Cervical Loop and the predicate device. The static tests results show the OMI® Occipital Cervical Loop to have higher stiffness and static strength than the predicate device. There were no device failures during the static tests. The fatigue tests results show the OMI® Occipital Cervical Loop outperformed the predicate device at all load levels tested. The OMI® Occipital Cervical Loop failure trend was rod bending/fracture, with the predicate device failure trend being rod bending.

II. 510(k) SUMMARY AND CERTIFICATION - continued

7. Packaging:

All OMI® Occipital Cervical Loops and instruments are supplied in industry standard medical grade packaging suitable for surgical implants and instruments. Shippers and boxes are of suitable design and materials to ensure product identification and protection from damage during shipping and storage.

8. Sterilization:

All OMI® Occipital Cervical Loops and instruments are supplied **NON-STERILE**. These non-sterile implants are packaged in "clean" condition, after processing to remove manufacturing residue and debris. All OMI® Occipital Cervical Loops and instruments must be removed from their shipping and packing materials, then washed and rinsed thoroughly, and sterilized before they may be used.

The recommended sterilization method, time and temperature for the OMI® Occipital Cervical Loops and instruments is gravity steam sterilization for 30 minutes at 121° C (250° F). The Sterility Assurance Level (SAL) of the recommended sterilization cycle is 10^{-6} (SAL 10^{-6}). Validation of the recommended sterilization cycle has been conducted by Surgicraft, Ltd. for the Ransford Cervical Fixation System™, and will be valid for the substantially equivalent OMI® Occipital Cervical Loops and instruments. Independent validation of this sterilization cycle, or an equivalent cycle, using method AAMI-TIR-12-1994, will be completed by OMI for the OMI® Occipital Cervical Loop and instrument prior to offering them for sale.

9. Conclusion:

Static tests and fatigue tests were conducted comparing the OMI® Occipital Cervical Loop to the Ransford Cervical Fixation System™. The results are discussed below.

Five (5) static tests and six (6) fatigue tests were run of each of the OMI® Occipital Cervical Loop and the predicate device. The static tests results show the OMI® Occipital Cervical Loop to have higher stiffness and static strength than the predicate device. There were no device failures during the static tests. The fatigue tests results show the OMI® Occipital Cervical Loop outperformed the predicate device at all load levels tested. The OMI® Occipital Cervical Loop failure trend was rod bending/fracture, with the predicate device failure trend being rod bending.

Based on the information provided above, Ohio Medical Instrument Company, Inc. considers the OMI® Occipital Cervical Loop to be equivalent to the predicate device.

II. 510(k) SUMMARY AND CERTIFICATION - continued

10. Comparison Table

FEATURE	OMI® Occipital Cervical Loop	Ransford Cervical Fixation System™	SE?
Intended Use:	<ul style="list-style-type: none"> • Surgical stabilization alone and surgical stabilization and fusion of the cervical spine and cervical occipital junction. 	<ul style="list-style-type: none"> • Surgical stabilization alone and surgical stabilization and fusion of the cervical spine and cervical occipital junction. 	YES
Indications for Use:	<ul style="list-style-type: none"> • Degenerative disk disease of the cervical vertebrae [neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiological studies], • Spondylolisthesis of the cervical vertebrae, • Spinal stenosis of the cervical vertebrae, • Atlanto/axial fracture with instability, • Cervical-occipital dislocation, • Revision of previous cervical fusion surgery, • Tumors. 	<ul style="list-style-type: none"> • Degenerative disk disease of the cervical vertebrae [neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiographic studies], • Spondylolisthesis of the cervical vertebrae, • Spinal stenosis of the cervical vertebrae, • Atlanto/axial fracture with instability, • Cervical-occipital dislocation, • Revision of previous cervical spine surgery, • Tumors. 	YES
Materials:	<ul style="list-style-type: none"> • Titanium. 	<ul style="list-style-type: none"> • Titanium or stainless steel. 	YES
Surgical Approach:	<ul style="list-style-type: none"> • Posterior. 	<ul style="list-style-type: none"> • Posterior. 	YES
Method of Attachment:	Wires to occiput and posterior arches.	<ul style="list-style-type: none"> • Wires to occiput and posterior arches. 	YES
K-Number:	<ul style="list-style-type: none"> • K983282 	<ul style="list-style-type: none"> • K965221 	YES
Manufacturer:	Ohio Medical Instrument Company, Inc.	Surgicraft, Ltd.	YES



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kenneth B. Miller
Regulatory Affairs and Quality Assurance Director
Ohio Medical Instrument Company, Inc. (OMI)
4900 Charlemar Drive
Cincinnati, Ohio 45227

Re: K983282
OMI® Occipital Cervical Loop
Regulatory Class: II
Product Code: KWP
Dated: September 17, 1998
Received: September 18, 1998

Dear Mr. Miller:

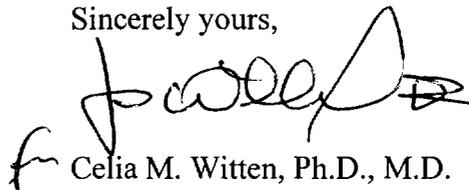
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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 requirements, 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is stylized and includes a large, sweeping 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 (if known): K983282

Device Name: OMI® Occipital Cervical Loop

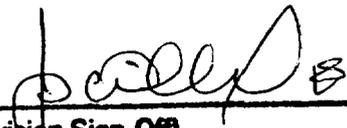
Indications For Use:

The OMI® Occipital Cervical Loop is intended to be used to assist stabilization and fusion of the cervical spine and cervical occipital junction.

1. Degenerative disk disease of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disk as confirmed by patient history and radiological studies).
2. Spondylolisthesis of the cervical vertebrae.
3. Spinal stenosis of the cervical vertebrae.
4. Atlanto/axial fracture with instability.
5. Cervical-occipital dislocation.
6. Revision of previous cervical fusion surgery.
7. Tumors.

(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 K983282

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format - 1 - 2 - 96)