K991662
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Section 510(k) Premarket Notification SURGICRAFT, LIMITED	Summary of Safety and Effectiveness Information for the TITANIUM HARTSHILL SYSTEM

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

1. Device Name:

TRADE NAME: **TITANIUM HARTSHILL SYSTEM**

Common Name: Spinal implant

Classification Name: Appliance, Fixation, Spinal Interlaminar

2. Establishment Name & Registration Number:

Name: SURGICRAFT, LTD.

Number: 8020712

3. Classification:

§ 888.3050 Spinal interlaminal fixation orthosis. (a) Identification. A spinal interlaminal 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.

Product Code: 87KWP

Device Class: Class II

Classification Panel: Orthopaedics and rehabilitation devices panel

5. Contact Person:

Mr. Simon Fitzer
SURGICRAFT, LIMITED
REDDITCH, WORCESTERSHIRE
B97 6HF, ENGLAND
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6. Special Controls:

Special controls have not been established for this device.

7. Device Description:

The **TITANIUM HARTSHILL SYSTEM** consists of the following items:

REF	SIZE
HTR 4025	4mm x 25mm
HTR 4035	4mm x 35mm
HTR 4045	4mm x 45mm
HTR 4065	4mm x 65mm
HTR 4075	4mm x 75mm
HTR 4085	4mm x 85mm

Surgical instruments designed to implant the device are also available.

Fixation Wire and Braided Fixation Cable are available in both stainless steel and titanium alloy for use with the appropriate implant type.

8. Substantially Equivalent Device(s):

The **TITANIUM HARTSHILL SYSTEM** is substantially equivalent to the following device:

1. Stainless steel Hartshill Spinal Fixation System - K853033

9. Comparison to Predicate Device(s):

Surgicraft, Ltd. currently manufactures a legally marketed device for the same indications called the stainless steel Hartshill Spinal Fixation System. The United States Food and Drug Administration previously reviewed a 510(k) submission for the Hartshill device (K853033). The FDA agreed that the Hartshill device was substantially equivalent to other preamendment spinal fixation systems and cleared it for marketing. The **TITANIUM HARTSHILL SYSTEM** intended for the identical indications cleared for the Hartshill device.

Both the stainless steel Hartshill Spinal Fixation System and the **TITANIUM HARTSHILL SYSTEM** are posterior attachment surgical approach systems. Both are used to treat the same medical conditions. Both have essentially the same cautions and contraindications for use. Both are basic spinal rod, crosslink and sublaminar wire systems. Both systems may be attached via bore holes wires.

The use of long established engineering and design principles (sublaminar wires and contoured rods) which most physicians are already extensively experienced, should contribute to the expected safety and effectiveness performance of the **TITANIUM HARTSHILL SYSTEM** system. The **TITANIUM HARTSHILL SYSTEM** utilizes similar implant materials meeting various BS, ISO and ASTM standards.

Testing and clinical performance demonstrate that **TITANIUM HARTSHILL SYSTEM** will perform substantially the same as the stainless steel Hartshill Spinal Fixation System (K853033).

10. Clinical Experience:

Summary and Conclusions: A review of peer literature concerning physiological loading of the cervical spine, together with the available mechanical test data comparing the **Titanium Hartshill SYSTEM** to the literature and the substantially equivalent predicate device give an assurance that the **Titanium Hartshill SYSTEM** is both safe and effective when used for the indications given.

11. Packaging:

All implants and instruments are supplied packaged in industry standard medical grade packaging suitable for surgical implants and instruments. Shippers and boxes are of suitable design and materials to ensure protection and identification during shipping and storage.

12. Sterilization/Re-sterilization:

All implants are supplied sterile by gamma irradiation to an SAL of 10^{-6}. Instruments are supplied non-sterile. Implants are processed to remove manufacturing residue

and debris. All implants and instruments should be removed from shipping and packing materials then washed and rinsed thoroughly before sterilization.

The labeling of the implants & instruments clearly indicates their sterility status. The package insert found in Appendix I specifies the recommended sterilization/re-sterilization cycle.

The recommended sterilization method, time and temperature for the implants is gravity steam sterilization for 45 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 cycle has been conducted by qualified commercial laboratories. The validation method used is known as the overkill method.

The recommended sterilization method is based on Health Industry Manufacturers Association (HIMA) & Association of Operating Room Nurses (AORN) protocols. Only the recommended sterilization cycle was validated.

13. Conclusion:

Based on the materials, intended uses, design, and effectiveness, the **TITANIUM HARTSHILL SYSTEM™** unit is substantially equivalent to the referenced legally marketed Stainless steel Hartshill Spinal Fixation System. The feature comparison chart below graphically demonstrates this equivalence.

14. Comparison Table:

FEATURE	TITANIUM HARTSHILL SYSTEM™	Stainless steel Hartshill Spinal Fixation System™	SE?
Intended Use:	Surgical stabilization and fusion of the cervical spine for the correction of spinal deficiencies.	Same cervical intended use.	Yes
Indications For Use:	Spinal deformity Spinal tumors Spinal fracture Dislocations Subluxations Spondylolisthesis	Same cervical indications for use.	Yes
Materials:	Titanium and stainless steel	Stainless steel	Yes
Surgical Approach:	Posterior	Posterior	Yes
Method of Attachment:	Wires /cable to posterior arches	Wires to posterior arches	Yes
K-Number	NA	K853033	Yes
Manufacturer:	Surgicraft, Ltd.	Surgicraft, Ltd.	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 1999

Mr. A. J. Fennell
Commercial Director
Surgicraft, Limited
Fishing Line Road
Redditch, Worcestershire
B97 6HF, England

Re: K991662
Trade Name: Titanium Hartshill System
Regulatory Class: II
Product Code: KWP
Dated: September 27, 1999
Received: September 30, 1999

Dear Mr. Fennell:

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,

for 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): K991662

Device Name: **TITANIUM HARTSHILL SYSTEM™**

Intended Use:

Surgical stabilization and fusion of the cervical spine for the correction of spinal deficiencies.

Indications For Use:

1. Spinal deformity
2. Spinal tumors
3. Spinal fracture
4. Dislocations
5. Subluxations
6. Spondylolisthesis

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991662

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)