

<b>Section 510(k) Premarket Notification SURGICRAFT, LIMITED</b>	<b>Summary of Safety and Effectiveness Information for the RANSFORD CERVICAL FIXATION SYSTEM™</b>
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**Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92

**1. Device Name:**

TRADE NAME: RANSFORD CERVICAL FIXATION SYSTEM™ AUG - 7 1997  
Common Name: Cervical spinal implant  
Classification Name: Appliance, Fixation, Spinal Interlaminar

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

Name: SURGICRAFT, LTD.  
Number: 8020712

**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.

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  
01527 66331 VOICE  
01527 65295 FAX

**6. Special Controls:**

Special controls have not been established for this device.

## 7. Device Description:

### Cleared Intended Use:

Surgical stabilization to assist bony fusion of the cervical spine and cervical occipital junction.

### Cleared 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 radiographic 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 spine surgery
7. Tumors

The **RANSFORD CERVICAL FIXATION SYSTEM™** consists of the following items:

HRL 4010 - Randsford Loop 100° OC Angle, 10mm Stainless Steel  
HRL 4015 - Randsford Loop 100° OC Angle, 15mm Stainless Steel  
HRL 4020 - Randsford Loop 100° OC Angle, 20mm Stainless Steel  
HRL 4045 - Randsford Loop 100° OC Angle, X-long, 10mm SS (w/3 cross links)  
HRL 3201 - Randsford Loop, pediatric size - (multi-waisted design)  
HRLR 4009 - Randsford Loop 90% 100° OC Angle, 9mm Stainless Steel  
HRLR 4013 - Randsford Loop 90% 100° OC Angle, 13mm Stainless Steel  
HRLR 4018 - Randsford Loop 90% 100° OC Angle, 18mm Stainless Steel  
HRLC 4150 - Stainless Steel Cross Link

HTL 4410 - Randsford Loop 100° OC Angle, 10mm Ti  
HTL 4415 - Randsford Loop 100° OC Angle, 15mm Ti  
HTL 4420 - Randsford Loop 100° OC Angle, 20mm Ti  
HTL 4445 - Randsford Loop 100° OC Angle, X-long, 10mm Ti (w/3 cross links)  
HTLR 4409 - Randsford Loop 90% 100° OC Angle, 9mm Ti  
HTLR 4413 - Randsford Loop 90% 100° OC Angle, 13mm Ti  
HTLR 4418 - Randsford Loop 90% 100° OC Angle, 18mm Ti

HTL 4610 - Randsford Loop 115° OC Angle, 10mm Ti  
HTL 4615 - Randsford Loop 115° OC Angle, 15mm Ti  
HTL 4620 - Randsford Loop 115° OC Angle, 20mm Ti  
HTL 4645 - Randsford Loop 115° OC Angle, X-long, 10mm Ti (w/3 cross links)

HTLR 4609 - Randsford Loop 90% 115° OC Angle, 9mm Ti  
HTLR 4613 - Randsford Loop 90% 115° OC Angle, 13mm Ti  
HTLR 4618 - Randsford Loop 90% 115° OC Angle, 18mm Ti

HTRLC 4450 - Titanium Cross Link

Surgical instruments designed to help implant the device are also available.

These implants are designed for use with annealed stainless steel wire 0.9mm diameter (20swg). This wire is the same wire cleared for use with the Hartshill Rectangle Spinal devices and is supplied by Surgicraft, Ltd.

Titanium alloy implants are designed for use with multi-filament braided titanium alloy (6Al,4V) cable, 0.045 inch (1.1mm) diameter, 19 inches long with a 3 inch, soft, pure titanium mono-filament lead wire. This wire is the same type of wire cleared for use with Sofamor/Danek spinal devices.

#### 8. Substantially Equivalent Device(s):

The **RANSFORD CERVICAL FIXATION SYSTEM™** is substantially equivalent to the following device:

##### 1. Hartshill Spinal Fixation System - K853033

#### 9. Comparison to Predicate Device(s):

Surgicraft, Ltd. currently manufactures a legally marketed device for the same indications as the Ransford Loop. That other device is listed above. A 510(k) Premarket Notification for the Hartshill device established the substantial equivalence of that system in 1985 to earlier preamendment spinal fixation systems. The **RANSFORD CERVICAL FIXATION SYSTEM™** is substantially equivalent to the earlier Hartshill Spinal Fixation System.

Both the Hartshill Spinal Fixation System 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 bore holes and wires.

Evolutionary development of long established engineering, design and medical treatment principles combines to offer predictable clinical performance for the requested cervical indications. The system is based on sublaminar wires and contoured rods placed posteriorly. This concept has been in common use for more than 35 years. Most orthopaedic and neurosurgeons physicians are already extensively experienced in these techniques and may be expected to adapt readily to the **RANSFORD CERVICAL FIXATION SYSTEM™**. Like the equivalent Hartshill system, the **RANSFORD CERVICAL FIXATION SYSTEM™** utilizes similar implant materials meeting various BS, ISO and ASTM standards.

Comparison testing and existing clinical performance demonstrates that the **RANSFORD CERVICAL FIXATION SYSTEM™** performs substantially the same as the earlier Hartshill Spinal Fixation System (K853033). However, pre-contouring of the Ransford implants and the addition of advanced materials offers evolutionary improvements over the Hartshill and other older systems.

#### 10. 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.

#### 11. Sterilization/Re-sterilization:

All implants and instruments are supplied **Non-Sterile**. Non-sterile implants are packaged in "clean only" condition. Implants are processed to remove manufacturing residue and debris only. All implants and instruments must be removed from their shipping and packing materials then washed and rinsed thoroughly before first use. Sterilization processing is required before the devices may be used.

The recommended sterilization method, time and temperature for the implants 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 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.

## 12. Conclusion:

Static tests were conducted contrasting the **RANSFORD CERVICAL FIXATION SYSTEM™** with the Hartshill Spinal Fixation System.

**Axial Torsion.** From the axial torsion tests conducted it was concluded that there is no statistically significant difference in stiffness, torque at gross failure and angular rotation at gross failure of the titanium Ransford Loop compared to the stainless steel Hartshill Cervical Rectangle. The mean stiffness and torque at gross failure are both higher for the titanium Ransford Loop than the stainless steel Hartshill Rectangle and the mean angle at gross failure is lower in the titanium Ransford Loop than the stainless steel Hartshill Cervical Rectangle.

**Axial Extension.** From the axial extension tests conducted it was concluded that there is a statistically significant increase in stiffness, increase in the force at gross failure and decrease in the extension at gross failure of the titanium Ransford Loop compared to the stainless steel Hartshill Cervical Rectangle. This is believed to enhance the clinical performance of the Ransford Loop compared to the contoured Hartshill Cervical Rectangle.

**Axial compression.** From the axial compression tests conducted it was concluded that there is a statistically significant increase in stiffness, increase in the force at gross failure and increase in the extension at gross failure of the titanium Ransford Loop compared to the stainless steel Hartshill Cervical Rectangle. This is believed to enhance the clinical performance of the Ransford Loop compared to the contoured Hartshill Cervical Rectangle.

**Cable/Wire Tensile Test.** From the tensile tests conducted it was concluded that there is a statistically significant increase in stiffness and force at gross failure of the titanium cables compared to the stainless steel wires. The tests also demonstrate that the wires have a longer extension to gross failure than the cables.

Based on a comparison of the device materials, intended uses, surgical technique, implant design, and comparison testing, the **RANSFORD CERVICAL FIXATION SYSTEM™** is substantially equivalent to the referenced legally marketed Hartshill Spinal Fixation System. The feature comparison chart below graphically illustrates such equivalence.

13. Comparison Table:

FEATURE	RANSFORD CERVICAL FIXATION SYSTEM™	Hartshill Spinal Fixation System™	SE?
<b>Intended Use:</b>	Surgical stabilization alone and surgical stabilization and fusion of the cervical spine and cervical occipital junction.	Same cervical intended use.	Yes
<b>Indications For Use:</b>	Degenerative disk disease of the cervical vertebrae (neck pain of discogenic origin with degeneration of the disc 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	Same cervical indications for use.	Yes
<b>Materials:</b>	Titanium and stainless steel	Stainless steel	Yes
<b>Surgical Approach:</b>	Posterior	Posterior	Yes
<b>Method of Attachment:</b>	Wires to occiput and posterior arches	Wires to occiput and posterior arches	Yes
<b>K-Number</b>	K965221	K853033	Yes
<b>Manufacturer:</b>	Surgicraft, Ltd.	Surgicraft, Ltd.	Yes



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. David W. Schlerf  
Buckman Company Inc.  
1000 Burnett Avenue, Suite 450  
Concord, California 94520

AUG - 7 1997

Re: K965221  
Ransford Loop Cervical Fixation System  
Regulatory Class: II  
Product Code: KWP  
Dated: July 27, 1997  
Received: July 29, 1997

Dear Mr. Schlerf:

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). 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 would cause the device system to be adulterated under 501(f)(1) of the Act.

FDA identifies that any device system, if intended for use in pedicular screw fixation/attachment, except for some limited indications, would be found not substantially equivalent and would be 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. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the package insert must include the following statement, "**WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.";
2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for the specific use(s) described in the enclosure only; and
3. Pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column, except for limited indications, of any device system 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 system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

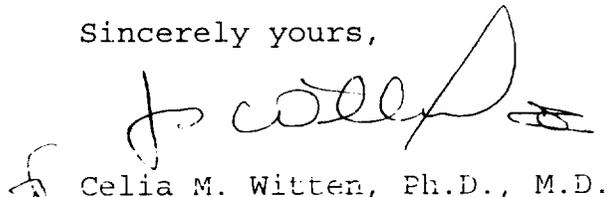
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

FDA advises that the use of the subject device system and/or device components 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 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 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

510(k) Number (if known): K965221

Device Name: **RANSFORD CERVICAL FIXATION SYSTEM™**

Intended Use: .....

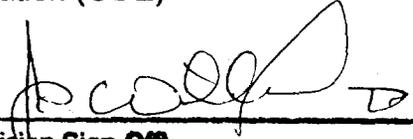
Surgical stabilization to assist bony fusion of the cervical spine and cervical occipital junction.

**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 radiographic 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 spine surgery
7. Tumors

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 K965221

Prescription Use X

OR

Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional format 1-2-96)