K960451

APR 18 1996

Summary of Safety and Effectiveness Information
(releasable upon request only)

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact

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Establishment Registration Number: **2242816**

Device Name:

Trade Name: **Webb-Morley Spine System**

Common Name(s): Pedicular Spine System

Classification Name(s): Spondylolisthesis Spinal Fixation Device System

Classification Code(s): **87MNH**

Substantially Equivalent Device(s)

1. **TSRH® Posterior Spine System**
   Sofamor/Danek
   K932029

2. **Posterior Lumbar Sacral Attachment (PLSA) Spine System**
   Advanced Spine Fixation Systems
   K945064

Device Description

Background. This document summarizes safety and effectiveness information about the **Webb-Morley Spine System**. The full information is contained in the 510(k) Premarket Notification submitted to FDA in support of EBIs' request for a finding of Substantial Equivalence.

The **Webb-Morley Spine System** is made from surgical implant grade Stainless steel meeting ASTM F-138-86 requirements. Stainless steel of this type is particularly well suited for use as surgical implants. In addition to excellent strength, fatigue and corrosion resistance characteristics, stainless steel has a very long history of use in the human body as an implant material.

The **Webb-Morley Spine System** has the same indications for use as the recently cleared TSRH® and PLSA systems. This indication for use is:

Reduction and stabilization of grades III & IV spondylolisthesis of the fifth lumbar to first sacral vertebral interspace only. The **Webb-Morley Spine System** is for temporary use and must be accompanied by the application of autogenous source bone graft only. Once solid fusion is achieved, surgical removal of the device system is recommended. Planned removal of the device occurs within one year of the original surgery in adults and within two years of reaching skeletal maturity for adolescents.

The use of the **Webb-Morley Spine System** as a pedicle screw system involves screw attachment at the sacrum, the L5 vertebral pedicles, the L4 vertebral pedicles and in isolated cases, the L3 vertebral pedicles. The inclusion of additional pedicular levels may sometimes be necessary in order to reduce the spondylolisthetic deformity at L5 - S1 and maintain adequate correction.

The Screws of this system are limited to L3-S1 or iliac screw fixation.

Contraindications. The existence of the following diseases or medical conditions generally excludes candidates from treatment with this type of spinal implant system.

A. Patients with spinal infection or inflammation
B. Morbid obesity
C. Mental illness, alcoholism, drug abuse
D. Pregnancy
E. Metal sensitivity or foreign body sensitivity
F. Patients with inadequate tissue coverage at the operative site
G. Open wounds local to the operative area

As an additional precaution, the **Webb-Morley Spine System** should only be implanted by surgeons fully experienced in the use of such implants and the required specialized spinal surgery techniques. Instructional course demonstrations and/or bio-skills workshops demonstrating the use of the **Webb-Morley Spine**

System implants may be offered following a finding of substantial equivalence by the FDA.

A comprehensive list of indications, contraindications, adverse effects, warnings and precautions may be reviewed in the package insert supplied with the system. Only the package insert is to be considered definitive or accurate in terms of system applications, uses or restrictions.

Packaging:

All packaging is commercially available industry standard items and is sufficient in design and material quality to provide durable identification and protection from physical damage during transportation and storage. The type of packaging used is essentially the same as that used for the TSRH® and the PLSA systems.

Sterilization/Re-sterilization:

All instruments and implants are supplied **Non-Sterile.** Device packages clearly indicate the sterility status of the contained component. Steam autoclave sterilization is the only processing method recommended for the **Webb-Morley Spine System**. A cleaning and validated sterilization process recommendation is located in the product package insert. Please obtain and review the package insert before using the system. 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.

Summary of Physical Testing:

Device and system testing consisted of static testing and comparison fatigue testing against the TSRH® system. The results of both modes of testing revealed that the **Webb-Morley Spine System** is suitable for the cleared indications and the anticipated physiologic loads imposed on the system. Comparison test values for the Webb-Morley system and the TSRH® system implants are equivalent.

Static testing showed that the **Webb-Morley Spine System** has sufficient strength to perform in a functionally equivalent manner to the comparison device systems. The **Webb-Morley Spine System** demonstrates excellent fatigue and strength characteristics. Based on the testing, the **Webb-Morley Spine System** is equal or superior in performance to the TSRH® Spine System.

Equivalence:

The table concluding this section summarizes available information for the comparison devices. The Substantially Equivalent devices and the **Webb-Morley Spine System** are all posterior surgical approach systems. All are used to treat similar or the same conditions. All have essentially the same cautions and contraindications for use. All have the same labeling warnings imposed by FDA. All are basic spinal rod, transverse interconnection and pedicle/sacral bone screw posterior spinal systems.

Design of the rods and pedicle screws of the **Webb-Morley Spine System** do not represent a significant departure from long established designs in terms of safety or effectiveness. The **Webb-Morley Spine System** utilizes identical implant materials (stainless steel) meeting BS, ISO and ASTM standards.

Conclusion:

The design features of the **Webb-Morley Spine System** are equivalent to those offered by the TSRH® and PLSA systems. Components of the comparable systems are all made from the same or equivalent implant grade materials. Device testing, engineering review, and comparison of the system components to the referenced devices demonstrates their functional engineering equivalence .

The **Webb-Morley Spine System** is currently distributed in the US, Europe and elsewhere in the world. Performance of the **Webb-Morley Spine System** for severe spondylolisthesis of L5/S1 is expected to be comparable to the TSRH® and PLSA devices.

Since the indications for use, system limitations and surgical techniques are well established and understood, spinal implant systems using such basic design elements may reasonably be expected to perform predictably. EBI uses current Good Manufacturing Practice regulations, in-house SOPs and appropriate ASTM standards to assure that the **Webb-Morley Spine System** performs predictably and is Substantially Equivalent. A summary feature comparison table follows.

FEATURE COMPARISON TABLE

FEATURE	Webb-Morley®	TSRH®®System	PLSA Spinal System	Substantial Equivalence
Surgical Approach:	Posterior	Posterior	Posterior	Yes
Materials:	316 LVM stainless steel	Titanium Alloy & 316 LVM Stainless Steel	Titanium Alloy	Yes
Indications for Use:	Severe Spondylolisthesis (Gr. III & IV) L5-S1, Degenerative Disc Disease, Fracture Dislocation	Same<	Same	Yes
Clinical Experience:	European	US & European	US & European	Yes
Hooks:	Laminar hooks, pedicle hooks, transverse process hooks	Same Types	Same Types	Yes
Rods	4.0mm round & 4.0mm X 6.0mm oval	1/4" & 3/16" rods	1/4" & 3/16"	Yes
Pedicular & Sacral Screws:	Cancellous threads 5.5mm, 6.5mm & 7.5mm	Same	Same	Yes
Meets BS, ISO & ASTM Standards:	BS-7252, ISO-5832-1 & ASTM F-138-86	F-138-86, Gr. 2 & F-136-92	F-136-92	Yes
Transverse Interconnection:	Yes	Yes	Yes	Yes
Sterilization Method:	Steam Sterilization per HIMA/AORN	Same	Same	Yes
Manufacturer:	Electro-Biology, Inc.	Sofamor/Danek	Advanced Spine Fixation Systems, Inc.	Yes
Classification Code:	87KWP & 87MNH	87KWP& 87MNH	87KWP & 87MNH	Yes
K-Number	NA	K932029	K945064	NA