

K974749 (p1 of 5)

510(k)
Summary of Safety and Effectiveness

MAR 13 1998

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

Company Name/Contact:

Regulatory Affairs Department
Cross Medical Products, Inc.
5160-A Blazer Memorial Parkway
Dublin, OH 43017-1339
614-718-0530, Fax 614-718-0540

Device Name:

Trade Name: SYNERGY™ Spinal System- Closed VLS™

Common Name(s): Anterior Spine Implants, Posterior Spine Implants, Universal Spine System

Classification Name(s):

Spinal Intervertebral Body Fixation Orthosis
Appliance, Fixation, Spinal Interlaminar
Spondylolisthesis Spinal Fixation Device System

Establishment Registration: 1526354

Classification:

The Orthopaedic and Rehabilitation Devices Panel assigned the unique device classification codes KWP and KWQ to this device system. The published physical description of these devices is in 21 CFR, 888.3050 and 888.3060. In addition, they are presently Class II medical devices. Class II medical devices are subject to Performance Standards. This device is also categorized under MNH (Spondylolisthesis Spinal Fixation), which is unclassified.

Performance Standards:

Performance Standards applicable to the Cross® Medical- SYNERGY™ Spinal System have not been published by FDA. Cross® Medical Products, Inc. produces this device according to the regulations and standards that are appropriate to the risk that Class II devices reasonably present. Voluntary performance standards, such as materials certifications, in-house SOP's and/or ASTM Standards are utilized as appropriate.

Substantially Equivalent Device(s):

1. SYNERGY™ Anterior Spinal System: K934429, K950709
2. SYNERGY™ Posterior Spinal System: K940631, K950099
3. SYNERGY™ Spinal System: K973836

Device Description:

Background: This document summarizes safety and effectiveness information for the SYNERGY™ Closed VLS™ contained in the 510(k) Premarket Notification submitted to FDA in support of its substantial equivalence.

Purpose: The SYNERGY™ Spinal System is intended to be used a part of a temporary construct that assists normal healing and is not intended to replace normal body structures. It is intended to help stabilize the spinal operative site during fusion procedures. It attaches to the spine posteriorly by means of hooks and/or screws joined with rods and anteriorly by means of vertebral screws joined with rods.

The posterior application components are grouped as follows:

1. INTEGRAL™ Open, Closed, Angled Closed and Reduction Screws, Variable Locking Screws with Variable Locking Seats, and Iliac Screws, with Hex Nuts and Set Screws. Only the INTEGRAL™ Open, Closed, Reduction and Variable Locking Screws are intended for pedicle fixation (see INDICATIONS).
2. Open and Closed Spinal Hooks with Sliders, C-Rings and Set Screws.
3. Adjustable and Fixed Transverse connectors with Set Screws.
4. Closed and Axial Rod Connectors with Set Screws.
5. Lateral Connectors with Set Screws.
6. Rods.
7. Instruments.
8. Sterilizer case(s).

The anterior application components are grouped as follows:

1. INTEGRAL™ Open and Closed Screws and Variable Locking Screws with Variable Locking Seats, with Hex Nuts and Set Screws.

2. Vertebral Washers.
3. Fixed Transverse Connectors with Set Screws.
4. Rods.
5. Instruments.
6. Sterilizer case(s).

Material: The implantable components may be made from either titanium or stainless steel. The titanium version consists of surgical implant grade titanium alloy as described by ASTM Standard F136 (Ti 6Al-4V ELI), and commercially pure titanium, grade 2 as described by ASTM Standard F67 (CP Ti, Gr. 2). The stainless steel version consists of surgical implant grade stainless steel as described by ASTM standard F1314 (22-13-5 Stainless Steel), and surgical implant grade stainless steel as described by ASTM standard F138, Grade 2 (316L Stainless Steel).

Indications for Use:

As a pedicle screw system, it is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; © who are having the screws fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. The levels of screw fixation are L3 to S1/Ilium.

As a posterior, non-pedicle screw and hook system, and an anterolateral, intervertebral body screw system, the specific indications are:

1. Degenerative Disc Disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Idiopathic scoliosis.
3. Kyphotic deformities of the spine.
4. Paralytic scoliosis and/or pelvic obliquity.
5. Lordotic deformities of the spine.
6. Neuromuscular scoliosis associated with pelvic obliquity.
7. Vertebral fracture or dislocation.
8. Tumors.
9. Spondylolisthesis.
10. Stenosis.
11. Pseudarthrosis.
12. Unsuccessful previous attempts at spinal fusion.

For posterior, non-pedicle screw use, the levels of use are T1 to the Sacrum/Ilium. For anterior use, the levels of use are T10 to L3 for the double rod constructs, and T5 to L5 for the single rod constructs.

Contraindications and Cautions:

The existence of the following conditions generally excludes candidates from treatment with spinal implants. Patients with rigid scoliotic curves vague spinal anatomy, bony abnormalities preventing safe screw fixation, metal sensitivities, morbid obesity, severe osteopenia, active localized infections or other disseminated infections (septicemia). In general, the SYNERGY™ Spinal System should only be implanted by surgeons fully experienced in the use of such implants and the required specialized spinal surgery techniques.

Note: The Cross® Medical- SYNERGY™ Spinal System Instrumentation Technique Manual should be carefully followed. It supplies important information on proper usage of the implants and instruments.

Packaging: All packages containing implants or instruments should be sealed and intact upon receipt. The product should not be used and should be immediately returned to Cross® Medical Products, Inc. if the package or product is damaged.

Sterilization:

The SYNERGY™ Spinal System is shipped non-sterile. All packaging materials must be removed prior to sterilization.

High temperature steam sterilization should be used, with the following cycle having been laboratory validated:

Method:	Steam
Cycle:	Gravity
Temperature:	250 degrees F (121 degrees C)
Exposure Time:	60 minutes

Note: It is recommended to dry and/or cool the parts to prevent condensation after the steam cycle.. Only sterile products should be used in the operative field.

The recommended sterilization cycle is based on HIMA/AORN protocols. Other sterilization methods and cycles may also be suitable. However, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

Product Complaints:

Any dissatisfaction with the product quality, labeling or performance should be reported to Cross® Medical Products, Inc. immediately by the customer or user. Furthermore, if any of the implants "malfunction," (i.e. do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, Cross® Medical Products, Inc. should be notified immediately by telephone, fax, or written correspondence.

When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint. In addition, the nature of the complaint should be clearly communicated along with a notification of whether a written report from Cross® Medical Products, Inc. is requested.

Instrumentation:

Three additional device specific instruments are necessary for insertion and anchoring of the SYNERGY™ Closed VLS™ that are not already part of the commercially available SYNERGY™ Spinal System. The instruments are made from stainless steel meeting ASTM A276, ASTM A564/A564M, and ASTM F899 standards. Established medical grade plastics (Ultem and Radel) and Silicone Rubber are used to construct the handles, cases, etc.

Substantial Equivalence:

The SYNERGY™ Closed VLS™ components are substantially equivalent to the SYNERGY™ Anterior and Posterior, Stainless Steel and Titanium Spinal System as cleared under K934429, K940631, K950099, K950709, and K973836.

All of these devices are used to treat similar or the same conditions, have essentially the same cautions and contraindications for use, and have equivalent potential for complications for risk of use. All represent a long standing, basic design concept and in terms of safety and effectiveness, differ only in minor details.

Conclusion:

Based on the basic design concept, the use of established well known materials, feature comparisons, mechanical testing, indications for use, surgical approach, preproduction quality assurance planning and engineering analysis, Cross® Medical Products, Inc. believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to existing legally marketed screws as components of universal spine systems.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Phil Mellinger
CROSS® Medical Products, Inc.
5160-A Blazer Memorial Parkway
Dublin, Ohio 43017-1339

MAR 13 1998

Re: K974749
SYNERGY™ Closed Variable Locking Screw (VLS™) Assembly
Regulatory Class: II
Product Codes: MNH, KWP, and KWQ
Dated: December 17, 1997
Received: December 19, 1997

Dear Mr. Mellinger:

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). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 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; and (d) who are having the device removed after the development of a solid fusion mass. 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 for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is 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. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 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; and (d) who are having the device removed after the development of a solid fusion mass.
2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

WARNINGS:

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:

device component fracture,
loss of fixation,
non-union,
fracture of the vertebra,
neurological injury, and
vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device 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 for pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.
4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

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.

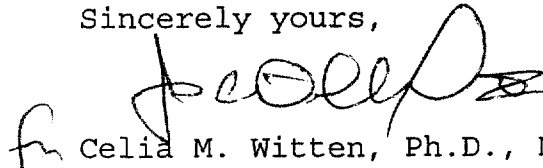
FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or those of other manufacturers, may also be required.

Page 4 - Mr. Phil Mellinger

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): K974749

Device Name: SYNERGY™ Spinal System- Closed VLS™

Indications For Use:

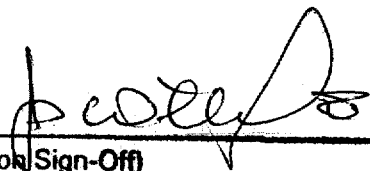
As a pedicle screw system, it is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; © who are having the screws fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. The levels of screw fixation are L3 to S1/Ilium.

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10. Stenosis.
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For posterior, non-pedicle screw use, the levels of use are T1 to the Sacrum/Ilium. For anterior use, the levels of use are T10 to L3 for the double rod constructs, and T5 to L5 for the single rod constructs.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974749

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____