OCT 1 2 2005 K051959

Confidential

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: NV CORMED
Aarschotsesteenweg 216
3130 Begijnendijk
BELGIUM

Device: SOLAS™ Spinal System

Classification Name: Pedicle Screw Spinal System (21CFR888.3070)

Intended Use: The SOLAS™, Spinal System is a pedicle screw based spinal fixation system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L5 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the SOLAS™ is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the SOLAS™ is indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

Device Description: The SOLAS™ Spinal System is a top-loading anterior / posterior spinal fixation system which consists of Mono and Polyaxial pedicle screws, rods, set screws, connectors, and a transverse (cross) linking mechanism. The *SOLAS™* implant components are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

The *SOLAS™* Spinal system can be used in both the anterior and posterior planes providing unilateral and bilateral modes of fixation.

The *SOLAS™* design allows adjustment in both the saggital and coronal planes permitting screw placement according to the best possible anatomic (spinal) location and orientation.
This is accomplished by means of a preassembled washer in the housing component between the screw and the rod which tightens against the head of the pedicle screw upon connection of the set screw with the rod.

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the *SOLAS™* implants.

Potential Risks: The potential risks associated with this device are the same as with any spinal fixation device. These include, but are not limited to:

Blood vessel damage	Bone fracture	Nerve damage
Deformity of the joint	Soft tissue complications	Infection
Cardiovascular disorders	Delayed wound healing	Hematoma
Component Failure	Metal sensitivity	Nerve impingement
Implant loosening/migration	Fracture of the components	Excessive wear

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2005

NV CORMED
c/o Carl Knobloch
Turnkey Integration USA
5349 Red Leaf Court
Oviedo, Florida 32756

Re: K051959
Trade/Device Name: SOLAS™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH, KWQ
Dated: July 17, 2005
Received: July 19, 2005

Dear Mr. Knobloch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

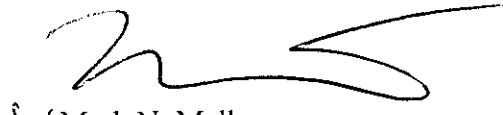
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K051959

Device Name: CORMED NV , *SOLAS*™, Spinal System

Indications for Use: The CORMED NV , *SOLAS*™, Spinal System is a pedicle screw based spinal fixation system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Prescription Use __X__ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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, and Neurological Devices

510(k) Number K051959

Page 1 of 1