K052385

DEC 2 7 2005

PREMARKET NOTIFICATION 510(K) SUMMARY

Company:	Ulrich GmbH & Co. KG Buchbrunnenweg 12 D-89081 Ulm Germany +49 (0) 731 9654-110/225 (phone) +40 (0) 731 9654-2702 (fax)
Company Contact:	Christoph Ulrich
Date:	August 26, 2005
Trade Name:	tangoRS Polyaxial System
Common Name	Pedicle Screw Spinal Fixation System
ClassificationCode:	Orthopedics, 888.3070, MNI, MNH, NKB
Device Description:	The tangoRS Polyaxial System includes screws (preassembled), a locking screw, rod and cross links.
Intended Use:	The tangoRS Polyaxial System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and sacral spine. When used as a posterior spine thoracic/lumbar system, the tangoRS Polyaxial System is intended for the following indications: degenerative disc disease (as defined by back pain of discogenic with degeneration of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., degenerative scoliosis, kyphosis, and/or lordosis), fracture, and spinal tumor.
Predicate Device:	Predicate device information is included.
Performance Data:	Performance data were submitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

Ulrich GmbH & Co. KG
c/o Ian Gordon
Senior Vice President
EmergoGroup, Inc.
2519 McMullen Booth Rd.
Clearwater, Florida 33761

Re: K052385
Trade/Device Name: tangoRS Polyaxial System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: August 26, 2005
Received: August 30, 2005

Dear Mr. Gordon:

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.

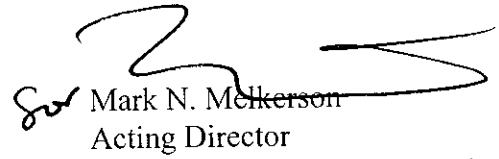
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indication for Use Statement

510(k) Number (if known): K052385

Device Name: tangoRS Polyaxial System

Indications for Use:

The tangoRS Polyaxial System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and sacral spine. When used as a posterior spine thoracic/lumbar system, the tangoRS Polyaxial System is intended for the following indications:

- degenerative disc disease (as defined by back pain of discogenic with degeneration of the disc confirmed by patient history and radiographic studies),
- spinal stenosis,
- spondylolisthesis,
- spinal deformities (i.e., degenerative scoliosis, kyphosis, and/or lordosis),
- fracture, and
- spinal tumor.

Prescription Use ____X____ or Over-The-Counter Use _____
(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 K052385