K120891
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OCT 1 2012

510(k) Summary

Date:	21 March 2012
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Contact Person:	Hans Stover ulrich medical USA, Inc. 612 Trade Center Blvd. Chesterfield, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax
Proposed Trade Name:	tangoRS™ multifunctional posterior system
Device Classifications:	Class II & Class III
Classification & Common Name:	Pedicle screw spinal system
Regulation:	888.3070
Device Product Code:	MNI, MNH, NKB
Device Description:	The tangoRS™ consists of rods, polyaxial pedicle screws and crosslinks with locking set screws. The components are available in various sizes to accommodate differing patient anatomy. Rods are available in one diameter and a variety of lengths. Polyaxial screws are available in a variety of diameter-length combinations. Crosslinks are offered in four lengths. The purpose of this submission is to add components (a screw size and crosslink options) and two indications for use.
Intended Use:	The tangoRS is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and sacral spine (T1-S2). When used as a posterior spine thoracic/lumbar system, the tangoRS 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, spinal tumor, pseudarthrosis and failed previous fusion.

Materials: The tangoRS™ components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.

Predicate Devices: flamenco™ (K102853)
CD HORIZON® (K031655/K041460)
Expedium (K041119/K062196)
tangoRS™ (K052385)

Technological Characteristics: tangoRS™ possesses the same technological characteristics as one or more of the predicate devices. These include:

- intended use (as described above)
- basic design (rod-based having screw anchors),
- material (titanium alloy),
- sizes (dimensions are comparable to those offered by the predicate systems) and

The fundamental scientific technology of tangoRS™ is the same as previously cleared devices.

Performance Data: Mechanical testing of the worst case tangoRS™ constructs included static and dynamic compression bending, and static torsion according to ASTM F1717.

The mechanical test results demonstrate that tangoRS™ performs as well as or better than the predicate devices and therefore that the device is as safe and as effective as the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ulrich GmbH & Company KG
% Ulrich Medical USA
Mr. Hans Stover
President & CEO
612 Trade Center Boulevard
Chesterfield, Missouri 63005

OCT 1 2012

Re: K120891
Trade/Device Name: tangoRS™ multifunctional posterior system
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: August 22, 2012
Received: August 23, 2012

Dear Mr. Stover:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120891

Device Name: **tangoRS™ multifunctional posterior system**

Indications for Use:

The tangoRS™ is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and sacral spine (T1-S2). When used as a posterior spine thoracic/lumbar system, the tangoRS 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, spinal tumor, pseudarthrosis and failed previous fusion.

Prescription Use X AND/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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120891