K101353

FEB - 4 2011

ulrich medical USA

510(k) Summary

Date:	**21 December 2010**
Sponsor:	**ulrich GmbH & Co. KG** Buchbrunnenweg 12 89081 Ulm Germany Phone: +49 (0) 731-9654-1304 Fax: +49 (0) 731-9654-2802
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:	golden gate™ System
Device Classification	Class II
Classification Name:	Spinal intervertebral body fixation orthosis
Common Name:	Anterior thoracolumbar plate system
Regulation:	888.3060
Device Product Code:	KWQ
Device Description:	The golden gate™ anterior plate system is used for the surgical stabilization and fixation of the thoracolumbar spine to provide a suitable environment for fusion to occur. The fixation components of the system include plates, screws and connectors (hex nuts and inlays). These are available in a variety of sizes and lengths to accommodate differing patient anatomy.
Intended Use:	The golden gate™ anterior plate system is intended to provide stabilization during the development of a spinal fusion. The golden gate™ system is indicated for use in the anterior/anterolateral thoracolumbar spine (T1-L5) for the treatment of: DDD (back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), Spondylolisthesis, Spondylolysis, Fracture (including dislocation or subluxation), Spinal stenosis, Deformities (i.e., scoliosis, kyphosis, lordosis), Tumor, Pseudarthrosis, Revision of previous surgery.
Materials:	The golden gate™ system components are manufactured from titanium alloy (Ti-6Al-4V) as described by ISO 5832-3 / ASTM F136.

Predicate Devices:	Kaneda SR (K971248) MACS TL (K002824 and K032059) Z-Plate (K922543)
Technological Characteristics:	The golden gate™ System possesses the same technological characteristics as the predicate devices. These include basic design (rod/plate-based screw system), material (titanium or titanium alloy), sizes (rod/plate lengths and screw diameters and lengths are within the range(s) offered by the predicate systems) and intended use (as described above). The fundamental scientific technology of the golden gate™ System is the same as previously cleared devices.
Performance Data:	Static compression bending and torsion, and dynamic compression bending of the worst case golden gate™ construct was performed following ASTM F1717. The mechanical test results demonstrate that the golden gate™ System performs as well as or better than the predicate devices.
Conclusion:	The golden gate™ System is substantially equivalent to the devices referenced above and is therefore as safe and as effective for its intended use.

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

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ulrich GmbH & Co., KG
% ulrich medical USA, Inc.
Mr. Hans Stover
President and CEO
612 Trade Center Boulevard
Chesterfield, Missouri 63005

Re: K101353
Trade/Device Name: golden gate™ System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 22, 2010
Received: December 23, 2010

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: K101353

Device Name: **golden gate™ system**

Indications for Use:

The golden gate™ anterior plate system is intended to provide stabilization during the development of a spinal fusion. The golden gate™ System is indicated for use in the anterior/anterolateral thoracolumbar spine (T1-L5) for the treatment of:

- DDD (back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies),
- Spondylolisthesis,
- Spondylolysis,
- Fracture (including dislocation or subluxation),
- Spinal stenosis,
- Deformity (i.e., scoliosis, kyphosis, lordosis),
- Tumor,
- Pseudarthrosis,
- Revision of previous surgery

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 K101353