K090861

510(k) Summary

MAY 21 2010

Date Prepared: 21 May 2010

Submitter Information

Company Name and Address:	Contact Name:
ulrich GmbH & Co. KG Buchbrunnenweg 12 89081 Ulm Germany	Hans Stover, President and CEO ulrich medical USA 754 Spirit 40 Park Dr. St. Louis, MO 63005 USA Phone: 636-519-0268

Name of Device

- Trade Name: mambo™
- Common Name: Anterior Cervical System
- Classification Name and Reference:

Classification Name and Reference per Title 21 Code of Federal Regulation (CFR)	Product Code
Part 888, Orthopedic Devices, Subpart D – Prosthetic Devices, 888.3060, Spinal intervertebral body fixation orthosis	KWQ – Anterior Cervical System

Substantial Equivalence Claimed to Predicate Device

- Spider Cervical Plating System, K052292, X-Spine Systems
- CLSP, K945700, Synthes (USA)
- ABC2 Anterior Cervical Plating System, K974706 and K0000486, Aesculap® Inc.

Device Description

mambo™ is a modular implant system for the anterior operative stabilization of the cervical spine (C2 to C7), only, consisting of cranial, caudal and extension plates as well as bone and revision screws of different sizes. Settling and clamping screws can be chosen for use of the mambo plate as a load-sharing (dynamic) or load-bearing (rigid) plate. The anterior cervical plates range in size from 20 mm to 142 mm to accommodate one to five segments of fixation. Bone and revision screws are available in lengths ranging from 13 mm to 19 mm.

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Intended Use and Indications for Use

mambo™ is intended for anterior operative stabilization of the cervical spine, (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

- Degenerative disc disease (DDD), defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Technological Characteristics

mambo™ possesses the same technological characteristics as the predicate devices. These include basic design (plate-based screw system), material (titanium or titanium alloy), sizes (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 mambo™ is the same as previously cleared devices.

Performance Data

Static compression bending, tension bending and torsion, and dynamic compression bending of the worst case mambo™ construct was performed according to ASTM F1717. The mechanical test results demonstrated that mambo™ performs as well as or better than the predicate devices.

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 & Co. KG
% Mr. Hans Stover
President and CEO
ulrich medical USA
754 Spirit 40 Park Dr.
St. Louis, MO 63005

MAY 21 2010

Re: K090861
Trade/Device Name: mambo™
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 23, 2010
Received: March 24, 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

K090861

5.0 ODE Indications Statement

510(k) Number (if known):

Device Name: mambo™, Anterior Cervical System

Indications for Use:

mambo™ is intended for anterior operative stabilization of the cervical spine, C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with:

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- Failed previous fusion

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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 K090861

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