K080841 (pg. 1 of 1)

510(k) Summary

JUL 23 2008

Sponsor:	**ulrich GmbH & Co. KG** Buchbrunnenweg 12 89081 Ulm Germany Phone: +49 (0)731-9654-1304 Fax: +49 (0)731-9654-2802
Contact Person:	Merle Symes ulrich Medical USA 754 Spirit 40 Park Drive St. Louis, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax (314) 616-7116 Mobile
Proposed Trade Name:	cosmic™ System
Regulation	888.3070 – Pedicle Screw Spinal Fixation System
Device Product Code:	MNI, MNH
Device Description:	The cosmic™ System includes rods and pedicle screws in a variety of lengths and diameters and transverse stabilizers. The pedicle screw threads comprise a calcium phosphate coating.
Intended Use:	The cosmic™ system is intended for posterior, noncervical pedicle fixation as an adjunct to fusion for the following indications: severe spondylolisthesis (grades 3 and 4) at L5-S1, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).
Materials:	The cosmic™ System components are manufactured from titanium alloy (Ti-6Al-4V per ASTM F136 / ISO 5832-3). The calcium phosphate coating (Bonit®) is manufactured according to ISO 13779-2.
Substantial Equivalence:	Documentation was provided which demonstrated the cosmic™ System to be substantially equivalent to the previously cleared SSCS System. The substantial equivalence is based upon equivalence in basic design, intended use, indications, materials, anatomic sites and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

Ulrich GMBH & Company KG
% Ulrich Medical USA
Mr. Merle Symes
President and CEO
754 Spirit 40 Park Drive
St. Louis, MO 63005

Re: K080841
Trade/Device Name: cosmic™ System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: MNI, MNH
Dated: June 5, 2008
Received: June 9, 2008

Dear Mr. Symes:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

K080841

Statement of Indications for Use

510(k) Number (if known): *Unknown*

Device Name: cosmic™ System

Indications for Use:

The cosmic™ system is intended for posterior, noncervical pedicle fixation as an adjunct to fusion for the following indications: severe spondylolisthesis (grades 3 and 4) at L5-S1, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

Prescription Use: ___X___ AND/OR Over-the-Counter Use: _____
(21 CFR § 801 Subpart D) (21 CFR §07 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080841