K103814

MAR 17 2011

ulrich medical USA

510(k) Summary

Date:	**22 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:	pezo™ PEEK Cage Family
Device Classification	Class II
Classification Name:	Intervertebral body fusion device
Regulation:	888.3080
Device Product Code:	MAX
Device Description:	The pezo™ PEEK Cage Family is comprised of three principal interbody fusion cages. The **pezo-P** and **pezo-T** devices have a basic rectangular shape while the **pezo-A** devices have a basic kidney shape. All implants have a hollow center for placement of autograft. The pezo implants are available in an assortment of height, length, width and anteroposterior angulation combinations to accommodate a variety of anatomic requirements.
Intended Use:	pezo™ is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and with autograft to facilitate fusion.
Materials:	pezo™ components are manufactured from polyetheretherketone (PEEK Optima LT1) as described by ASTM F2026. Integral markers are manufactured from tantalum according to ASTM F560.

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Predicate Devices:	Lumbar I/F Cage® (P960025) Ray TFC™ Device (P950019) AVS PEEK Spacers (K073470, K082014, K083661 and K090166)
Technological Characteristics:	pezo™ possesses the same technological characteristics as one or more of the predicate devices. These include: • intended use (as described above) • basic design (hollow structure for the containment of autograft), • material (polymer), • sizes (dimensions are comparable to those offered by the predicate systems) and The fundamental scientific technology of pezo™ is the same as previously cleared devices.
Performance Data:	Mechanical testing of the worst case pezo™ device included static and dynamic compression according to ASTM F2077 and subsidence according to ASTM F2267. The mechanical test results demonstrate that pezo™ performs as well as or better than the predicate devices and therefore that the device is as safe and as effective as the predicates.

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

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Re: K103814
Trade/Device Name: pezo™ PEEK Cage Family
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 22, 2010
Received: December 29, 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,

for

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: K103814

Device Name: **pezo™ PEEK Cage Family**

Indications for Use:

pezo™ is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with supplemental fixation and with autograft to facilitate 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

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