510(k) SUMMARY

This 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87

OCT – 5 2009

Establishment Registration Number:	9612420
Address of Manufacturer:	ulrich GmbH & Co. KG Buchbrunnenweg 12 89081 Ulm, Germany
Contact Person:	Merle Symes President and CEO ulrich medical USA 754 Spirit 40 Park Drive Chesterfield, MO 63005
Date Prepared:	28 September 2009
Trade or Proprietary Name:	AddPlus™, Anterior Distraction Device Plus
Common or Usual Name:	Vertebral body replacement device
Classification Name:	Spinal intervertebral body fixation orthosis (21 CFR 888.3060) Product code: MQP Class II
Predicate Device Identification:	VBR™ (K012254)

Device Description:

The AddPlus™ is a modification of the 12 mm diameter VBR™ device cleared under K012254. It is an adjustable (distractable/retractable) cylindrical cage with attached fixation plates that add supplemental bilateral spinal fixation to the design of the marketed VBR™ device. The device remains constructed from medical grade titanium alloy. In the case of resected vertebral bodies

of the human spine, the AddPlus™ is used for bridging the intervertebral space and serves to lengthen the anterior column, realigning the spinal profile, to stabilize the anterior column, and to support the consolidation of inserted bone material.

The attached fixation plates serve to provide further fixation and stabilization and to prevent migration as well as possible sinking in of the implant. The device is available in one diameter (i.e., 12 mm), four expansion ranges (i.e., 13 – 18 mm, 17 – 26 mm, 25 – 41 mm, and 40 – 65 mm), and four angles (i.e., 0°, 6°, 12°, and 18°).

Available components to be used with the AddPlus™ include a locking screw, osmium™ screw, and cancellous bone screw. The locking screw is used to fix the height of the adjusted AddPlus™. The osmium™ screw is used for monocortical fixation. It is available in lengths of 14, 16, and 18 mm, with a diameter of 5 mm. The cancellous bone screw is used for bicortical fixation. It is available in lengths of 12, 14, 16, 18, 20, 24, and 26 mm, with a diameter of 4 mm. In addition to these device components, a number of surgical instruments are available for use during implantation of the device.

Intended use and comparison to predicate devices:

The AddPlus™ is a vertebral body replacement device intended for use in the thoracolumbar spine (T1 – L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture).

The AddPlus™ is intended to be used with supplemental internal fixation systems that are cleared by FDA for use in the thoracic and lumbar spine. Such systems include posterior pedical screw and rod systems, anterior plate systems, and anterior screw and rod systems.

The use of bone grafting material with the AddPlus™ is optional.

Technological characteristics and comparison to predicate devices:

A comparison of the subject and predicate devices identified technical differences in geometrical configurations. Similarity was noted with regards to material of construction.

The differences in technological characteristics between the subject and predicate devices do not raise new types of safety or effectiveness questions. Accepted scientific methods, such as performance (bench) testing, do exist for assessing the effect of the differences in characteristics.

Summary of performance data:

Mechanical testing, in accordance with applicable recommendations of FDA guidance titled "Guidance for Industry and FDA Staff, Guidance for Spinal Systems 510(k)s," dated May 2004, was conducted to demonstrate equivalence to the predicate devices and demonstrated the subject device's capability to withstand anticipated in vivo loads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ulrich GmbH & Company KG
% Ulrich Medical USA
Mr. Merle Symes
President and Chief Executive Officer
754 Spirit 40 Park Drive
Chesterfield, Missouri 63005

OCT - 5 2009

Re: K090841
Trade/Device Name: AddPlus™, Anterior Distraction Device Plus
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: September 28, 2009
Received: September 29, 2009

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 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 (240) 276-3150 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

510(k) Number (if known): K090841

Device Name: AddPlus™, Anterior Distraction Device Plus

Indications for Use:

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The AddPlus™ is intended to be used with supplemental internal fixation systems that are cleared by FDA for use in the thoracic and lumbar spine. Such systems include posterior pedical screw and rod systems, anterior plate systems, and anterior screw and rod systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X AND/OR Over-the-Counter Use: _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090841