JUL 2 1 2011

Section 5 – 510(k) Summary

Submitter:	icotec ag Industriestrasse 12 CH-9450 Altstaetten Switzerland
Contact Person:	Barbara Atzenhoefer Stegmeier Alquest, LLC 763 287 3830 (phone) 763 287 3836 (fax)
Date Prepared:	April 4, 2011
Trade Name:	ETurn Spinal Implant
Common Name:	Intervertebral body fusion device
Classification:	Class II, Intervertebral Body Fusion Device, 21 CFR 888.3080
Product Code:	MAX
Predicate Device(s):	Lumbar I/F Cage System (P960025) KIMBA™ Spinal Implant (K052533) KIMBA™ mini (K080349)
Device Description:	The icotec ETurn Spinal Implant is a hollow, curved frame spinal implant comprised of carbon fiber reinforced polyetheretherketone or CF/PEEK containing 62% ± 3% carbon fibers (by volume) with 50 µm tantalum threads, ≤ 0.5% (by volume). It consists of a windowed body with a central slot, a distraction/insertion wedge and surface treads on its cranial and caudal surfaces that serve to guide and anchor the implant. The smooth tread surface helps to create a significantly larger pressure-bearing contact surface between the implant and the bone than the conventional pointed anchoring elements.
Intended Use:	The ETurn spinal implant is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) in the lumbar spine at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level. The ETurn devices are to be used with autogenous bone graft. Patients should have had at least six (6) months of non-operative care prior to treatment with this device. The ETurn spinal implant is intended for use with supplemental fixation such as posterior fixation by pedicle screws and rods.
Functional and Safety Testing:	Finite Element Analysis (FEA) was performed to demonstrate mechanical performance similar to that of a legally marketed predicate device. The FEA was supported by static compression, dynamic compression and dynamic torsion testing performed per ASTM F2077. Particulate characterization was performed per ASTM F1877. Subsidence testing was also performed per ASTM F 2267. These preclinical tests demonstrated substantially equivalent performance of the ETurn device as compared to legally marketed predicate devices.
Conclusion:	Icotec considers the ETurn to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for 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

JUL 2 1 2011

Icotec AG
% Alquest, LLC
Ms. Barbara Atzenhoefer Stegmeier
4050 Olson Memorial Highway, Suite 350
Minneapolis, Minnesota 55422

Re: K100305
Trade/Device Name: ETurn Spinal Implant
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 18, 2011
Received: July 19, 2011

Dear Ms. Stegmeier:

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

K100305

Section 4 – Indications for Use Statement

PreMarket Notification Number: K100305

Device Name: ETurn Spinal Implant

Indications For Use:

The ETurn spinal implant is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) in the lumbar spine at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level. The ETurn devices are to be used with autogenous bone graft. Patients should have had at least six (6) months of non-operative care prior to treatment with this device.

The ETurn spinal implant is intended for use with supplemental fixation such as posterior fixation by pedicle screws and rods.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 K100305

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