K063461

2.0 510(K) SUMMARY FOR THE ANOVA CONTAINMENT DEVICE

Submission Date: November 15, 2006

Submitter Information:

Company: Anova Corporation
25 DeForest Avenue
Summit, NJ 07901

AUG 13 2009

Contact Person: Bret Ferree, M.D.
President and CEO
Tel: 513-817-7327
Fax: 513-871-3131

Correspondent Information:

Campbell Tuskey, M.S.P.H.
2001 Pennsylvania Avenue, NW
Suite 575
Washington, DC 20006
Tel: 202-822-1850
Fax: 202-822-1859

Device Information:

Trade Name: Anova Containment Device

Common Name: Surgical mesh
Spinal intervertebral body fixation orthosis

Classification: 21 CFR §878.3300 EZX
21 CFR §888.3060 KWQ

Device Class: Class II

Predicate Devices:

Trade Name:	MYSTIQUE™ Resorbable Graft Containment Plating System
Manufacturer:	MacroPore Biosurgery, Inc.
K Number:	K041105
Product Code:	KWQ
Trade Name:	OptiMesh™ 1500
Manufacturer:	Spineology, Inc.
K Number:	K014200
Product Code:	EZX
Trade Name:	Graft Containment Device
Manufacturer:	NuVasive, Incorporated
K Number:	K070148
Product Code:	KWQ

Intended Use: The Anova Containment Device, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

Device Description: The Anova Containment Device is a flexible, synthetic composite implantable mesh. It includes a polyester mesh component connected by a mono-filament suture to a porous expanded polytetrafluoroethylene or "ePTFE" component. This ePTFE component is placed between the polyester mesh and the overlying soft tissues. The ePTFE component is not anchored to the disc.

The Anova Containment Device is attached to the spine with four suture anchors (two fastened to the vertebra above and two fastened to the vertebra below the disc). The sutures from the anchors overlay the mesh and hold it against the vertebral body and to reinforce the mesh against pressure from the graft material.

Comparison to Predicate Devices:

The Anova Containment Device has the same intended use and similar technological characteristics as the predicate devices. Differences in the design and performance from the cited predicates do not affect either the safety and/or effectiveness of the Anova Containment Device for its intended use. The safety and effectiveness evaluations based on data provided in this 510(k) demonstrate that the Anova Containment Device is substantially equivalent to the cited predicate devices.

Conclusion:

The results of our evaluation of the Anova Containment Device support the conclusion that it is as safe and effective as legally marketed devices for its intended use and that because it has the same intended use and similar technology, it is substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Anova Corporation
% Becker & Associates Consulting, Inc.
Ms. Campbell T. Hutton, MSPH
2001 Pennsylvania Avenue, SW
Washington, District of Columbia 20006

AUG 18 2009

Re: K063461
Trade/Device Name: Anova Containment Device
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: EZX, KWQ
Dated: July 8, 2009
Received: July 8, 2009

Dear Ms. Hutton:

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

1.0 STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K_____

Device Name: Anova Containment Device

Indications for Use:

The Anova Containment Device, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

Caution: Federal law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the State in which he / she practices to use or order the use of the device.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063461