SECTION 5

FEB 2 7 2013

510(k) SUMMARY (21 CFR 870.92)
ReLeaf™ Catheter

510(k) Owner:	Vital 5 LLC 570 Research Park Way, Suite 102 North Logan, UT 84341 Tel: 435-752-0307 Fax: 435-213-4878
Contact Person:	T. Wade Fallin Tel: 435-752-0307 e-mail: wade@venturemd.com
Date Prepared:	August 29, 2012
Trade Name:	ReLeaf™ Catheter
Common Name:	Anesthesia Conduction Catheter and Apparatus Suction
Classification:	Class II (21 CFR 868.5120) and Class I (21 CFR 878.4680)
Product Code:	BSO and GCY
Predicate Device:	Axiom Multipurpose Wound Drain (K993592)
Device Description:	The ReLeaf catheter is comprised of a radiopaque multi-lumen catheter which bifurcates proximally into a single lumen wound drain line and a single lumen anesthetic infusion line. The distal tip of the device is composed of a thin film with one side for anesthetic infusion and the other for wound drainage. The anesthetic infusion and drainage sides of the catheter are clearly marked and mid-shaft depth markings are also present. Proximally the infusion and drain lines are both affixed to an insertion trocar.
Intended Use:	ReLeaf catheters are intended for use where a routine drainage tube is required to drain fluids and exudates during or after surgery. The additional lumens allow for application of anesthetic to relieve postoperative pain. The ReLeaf catheter indication statement is narrower than and fully encompassed by the predicate device's indications. Therefore

neither the therapeutic effect nor the safety and effectiveness are impacted.

Technological Characteristics:

The Vital 5 ReLeaf catheter has similar technological characteristics to the Axiom Multipurpose Wound Drain. Both devices have multiple lumens for infusion of anesthetics and drainage of fluids within the surgical wound and are manufactured from radiopaque materials allowing for assessment of catheter placement after wound closure.

The materials used to manufacture the two devices and their coatings are different however this does not impact safety or effectiveness as the full battery of ISO 10993 testing has been passed by the ReLeaf catheter. The distal tip of the catheters contain a design difference with the ReLeaf catheter flaring into a broad flat sheet and the predicate remaining cylindrical in shape however this does not impact safety or effectiveness as the performance of the ReLeaf catheter has been confirmed for its intended use in bench testing and simulated use animal testing.

Non-Clinical Performance Data:

Bench-top and animal testing was conducted to demonstrate that the differences in technological characteristics between the ReLeaf catheter and the predicate do not introduce any new issues of safety or effectiveness. Performance testing included insertion force, removal force, leak testing, patency, lumen compression, polymer leachables, fatigue strength, tensile strength, biocompatibility, tissue adherence and simulated use testing.

The performance testing results support a substantial equivalence determination by demonstrating that the ReLeaf catheter is safe and effective for its intended use.

Conclusions:

The ReLeaf catheter is substantially equivalent to the Axiom Multipurpose Wound Drain (K993592), regarding its intended use, indications for use and technological characteristics. No new issues of safety or effectiveness are introduced as a result of the differences in technological characteristics or indication statements.

Vital 5 LLC has determined that the ReLeaf catheter is substantially equivalent to the predicate device and safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Vital 5
% Mr. T. Wade Fallin
President and Chief Executive Officer
570 Research Park Way, Suite 102
North Logan, Utah 84341

February 27, 2013

Re: K122661
Trade/Device Name: Vital 5 ReLeaf Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia conduction catheter
Regulatory Class: Class II
Product Code: BSO, GCY
Dated: February 20, 2013
Received: February 21, 2013

Dear Mr. Fallin:

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

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4

Indications for Use Statement

510(K) Number (if know):_____K122661_____

Device Name: Vital 5 ReLeaf Catheter

Indications for Use:
ReLeaf catheters are indicated for use where a routine drainage tube is required to drain fluids and exudates during or after surgery. The additional lumens allow for application of anesthetic to relieve postoperative pain.

Prescription Use__**X**__ AND / OR Over-the-Counter Use ____
(21 CFR 801 Subpart D) (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)

Long H. Chen -S

Digitally signed by Long H. Chen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -S, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.02.27 08:04:19 -05'00'

(Division Sign-off)
Division of Surgical Devices
510(k) Number___K122661___