K093510

AUG 23 2010

510(k) SUMMARY

SonoSite LumenVu™ Catheter Guidance System

Submitter Information

Name and Address:	SonoSite, Inc. 21919 30th Drive SE Bothell, WA 98021
Contact Person:	Mary K. Moore, V.P. of Regulatory Affairs
Date Prepared:	November 10, 2009

Device Identification

Proprietary Name:	LumenVu™ Catheter Guidance System
Common Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Classification:	Accessory for Catheter Position General Hospital and Personal Use Therapeutic Devices 21 C.F.R. § 880.5970
Product Codes:	OMF

Predicate Device Information

NEO MAPcath Sensor Stylet (Corpak MedSystem) – K083121

FlowPICC Stylet (VasoNova, Inc.) – K081625

InfraReDx NIR Imaging System (InfraReDx, Inc.) – K052908

Intended Use / Indications for Use

The LumenVu™ Catheter Guidance System is intended to aid in the placement of peripherally inserted central catheters (PICC) by providing real-time visual navigation of the catheter tip. The system may be used by trained caregivers in hospitals or other healthcare facilities.

Technological Characteristics

The SonoSite LumenVu™ Catheter Guidance System consists of a control box, a display screen, a camera, and a sterile optical stylet. The system uses a near-infrared light source to provide immediate visual feedback to the user on the location of a peripherally inserted central catheter tip. The optical stylet replaces traditional stiffening wire and provides a path for NIR light to its tip.

Performance Data

Performance testing and engineering analysis was performed and submitted to characterize the components of the SonoSite LumenVu™ Catheter Guidance System. Test results demonstrated that the LumenVu™ System functioned as intended. The observed test results demonstrate that the LumenVu™ System is as safe and effective as the predicate devices. Testing demonstrated that the system meets the requirements of IEC 60601-1 for electrical safety, IEC 60601-1-2 for electromagnetic compatibility, and IEC 60825-1 for laser safety.

Substantial Equivalence

The SonoSite LumenVu™ Catheter Guidance System has the same intended use and similar indications as the predicate devices. Any minor differences in technological characteristics and principles of operation do not raise any new issues of safety or effectiveness. Thus, the SonoSite LumenVu™ Catheter Guidance System is substantially equivalent to the predicate devices.

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

Ms. Mary K. Moore
Vice President of Regulatory Affairs
SonoSite, Incorporated
21919 30th Drive SE
Bothell, WA 98021

AUG 23 2010

Re: K093510
Trade/Device Name: Lumen Vu™ Catheter Guidance System
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: OMF
Dated: August 19, 2010
Received: August 20, 2010

Dear Ms. Moore:

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,

Susan Runner

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093510

Indications for Use Statement

510(k) Number (if known): _____

Device Name: LumenVu™ Catheter Guidance System

Indications for Use:

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Prescription Use _X___ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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