510(k) Summary

K102595

DEC 27 2010

Submitter: MediStim ASA
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Contact Information: Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432
763-574-1976

Submission Date: September 3, 2010

Device Name and Classification: MediStim VeriQC System, Medical ultrasonic imaging and volume flow-meter with probes, Class II

Product Code:

	CFR Number	Product Code
Cardiovascular blood flowmeter	870.2100	DPW
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

Equivalent Device Identification:

The MediStim VeriQ^{C} is substantially equivalent to the MediStim VeriQ model VQ4122 (K040228) manufactured by MediStim ASA, Fernanda Nissensgate 3, N-0484 OSLO, with added features equivalent to the GE Vivid 7 Diagnostic Ultrasound System with Diagnostic ultrasound transducers (K041552) manufactured by GE Medical systems, Ultrasound and Care Diagnostics, LLC PO Box 414, Milwaukee, WI 53201.

Device Description:

The VeriQC system incorporates several ultrasound modalities that can be used during a variety of surgical interventions. The system utilizes the well established technology of transit-time flow measurements to accurately measure blood flow in veins and arteries intraoperatively. In addition, the system provides ultrasound echocardiography for intraoperative imaging of the cardiovascular circulatory system. The system supports both B-Mode (2D) grayscale imaging, color Doppler (CFM) and pulsed wave Doppler (PW-Doppler). The system also has the ability to connect other external physiological signals such as blood pressure, ECG and other auxiliary signals provided by other monitoring systems.

The VeriQC transducer selection includes both transit-time probes for blood flow measurements on various vessel sizes and types as well as an intraoperative imaging probe.

Intended Use:

The Medi-Stim VeriQC System is intended for use as an intraoperative system utilizing ultrasonography to visualize blood flow and to guide surgeons to successfully plan and accomplish surgical interventions. The clinical indications for the device are:

1. Accurate transit time blood volume and Doppler velocity flow measurements during cardiovascular-, vascular- and transplantation-surgery.
2. Simultaneous measurements of blood pressure, vascular resistance, interfaced physiological signals and other derived parameters during these procedures.
3. Detection of normal and abnormal blood volume and Doppler velocity flow patterns during these procedures.
4. Provides guidance to prepare surgical plans at the initiation of surgery and to support the successful accomplishment of surgery including detection and location of vessels during surgical procedures.
5. Detection and quantification of the degree of stenosis in arteries by using the Doppler velocity profile.

Comparison Table:

	MediStim VeriQ^C	MediStim VeriQ	GE Vivid 7
Indications for use	"The Medi-Stim VeriQ^C System is intended for use as an intraoperative system utilizing ultrasonography to visualize blood flow and to guide surgeons to successfully plan and accomplish surgical interventions." The clinical indications for the device are: 1) Accurate transit time blood volume and Doppler velocity flow measurements during cardiovascular-, vascular- and transplantation-surgery. 2) Simultaneous measurements of blood pressure, vascular resistance, interfaced physiological signals and other derived parameters during these procedures. 3) Detection of normal and abnormal blood volume and Doppler velocity flow patterns during these procedures. 4) Provides guidance to prepare surgical plans at the initiation of surgery and to support the successful	The Medi-Stim VeriQ System is an interaoperative diagnostic system that utilizes ultrasonography to guide surgeons to successfully plan and accomplish surgical interventions. The clinical indications for the device are: 1) Accurate transit time blood volume and Doppler velocity flow measurements during cardiovascular-, vascular-, transplantation- and neuro-surgery. 2) Simultaneous measurements of blood pressure, vascular resistance, interfaced physiological signals and other derived parameters during these procedures. 3) Detection of normal and abnormal blood volume and Doppler velocity flow during these procedures.	The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal (including renal and GYN); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic, Cardiac (adult and pediatric); Peripheral Vascular (PV); Musculo-skeletal Conventional;Urology (including prostate), Transesophageal; Transrectal (TR); Transvaginal (TV); and Interaoperative (abdominal, thoracic and vascular)

	accomplishment of surgery including detection and location of vessels during surgical procedures. 5) Detection and quantification of the degree of stenosis in arteries by using the Doppler velocity profile."	4) Provides guidance to prepare surgical plans at the initiation of surgery and to support the successful accomplishment of surgery including detection and location og vessels during surgical procedures 5) Detection and quantification of the degree of stenosis in arteries by using the Doppler velocity profile.	
Patient group	Adult and pediatric	Adult and pediatric	Neonatal, adult and pediatric
Ultrasound modalities	Transit-time, B-mode, Color Doppler, Power Doppler and PW Doppler ultrasound, Combined Mode.	Transit-time, PW Doppler	B-Mode, M-Mode, PW Doppler, Color Doppler, Color M Doppler, Power Doppler, Combined modes, Coded Pulse
Other inputs	Blood pressure, ECG, Auxiliary inputs	Blood pressure, ECG, Auxiliary inputs	Not available in summary

Summary of Testing: Testing included EMC, Safety testing and Acoustic Safety Measurements. The MediStim VeriQC has also been verified and validated according to functional and software requirements.

Conclusion: The indication for use statements of the two predicate devices with regard to patient groups and surgical procedures are equivalent to the indications for use statement of the Medi-Stim VeriQ^C System.

The main clinical applications for all devices are the same namely cardiovascular-, vascular-, and transplantation-surgery.

The technology platform for the VeriQ^C and the VeriQ predicate device are identical with respect to computing platform, operating system and TTFM acquisition hardware. The ultrasound front-end of the VeriQ^C is based on the same principles as the predicate GE device, providing a modern fully digitized ultrasound acquisition module. The devices share the same imaging modalities and base the acoustic safety system on the same principles.

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

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MediStim ASA
C/O Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432

Re: K102595
Trade/Device Name: MediStim VeriQC System
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: Class II (Two)
Product Code: DPW, IYO, IYN, and ITX
Dated: December 12, 2010
Received: December 15, 2010

Dear Ms. Bundy:

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K102595

510(k) Number (if known): K102595

DEC 27 2010

Device Name: MediStim VeriQC system

Indications For Use:
The Medi-Stim VeriQC System is intended for use as an intraoperative system utilizing ultrasonography to visualize blood flow and to guide surgeons to successfully plan and accomplish surgical interventions." The clinical indications for the device are:

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5. Detection and quantification of the degree of stenosis in arteries by using the Doppler velocity profile.

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 Cardiovascular Devices

510(k) Number K102595