2 510(k) Summary (K101239)

JUN - 2 2010

Date Prepared: May 21, 2010

2.1 Establishment Address and Registration

St. Jude Medical
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293
Establishment Registration Number: 2248049

2.2 Submitter's Name/Contact Person

Loucinda Bjorklund
St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN 55117 USA

2.3 Device Classification

Trade Name:	ViewFlex™ Plus ICE Catheter
Common Name:	Catheter
Classification Name:	892.1550, System, Imaging, Pulsed Doppler Ultrasonic; 892.1570, Transducer, Ultrasonic 892.1560, System, Imaging, Pulsed Echo, Ultrasonic 892.1200, Diagnostic Intravascular Catheter

2.4 Predicate Device

K073709 ViewFlex Plus ICE Catheter (St. Jude Medical)

2.5 Indications for Use

The ViewFlex Plus ICE Catheter, part of the ViewMate System, is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.

2.6 Device Description

The ViewFlex Plus ICE Catheter is a temporary intracardiac ultrasound catheter intended for use in patients to accurately visualize cardiac structures and blood flow within the heart when connected to a ViewMate II (Philips HD11 XE, cleared under K062247) ultrasound system via the Patient Isolation Module (cleared under K073709). The catheter shaft is 9 French, 90 cm radio-opaque Pebax tubing that is shipped sterile. The catheter offers a bi-directional curve with a deflection angle of at least 120 degrees each direction that can easily be manipulated with one hand by turning the black knob left or right. The transducer is in the neutral/straight position when the white line of the knob is aligned with the center white line on the handle. To move the transducer away from the image, turn the handle to the left. The steering mechanism engages

when the left arrow line is crossed. To move the transducer toward the structure of interest, turn the handle to the right. A 10F introducer is recommended for use with this catheter for insertion into the femoral or jugular veins. The catheter consists of a 64-element linear phased array transducer with a multiple frequency range between 4.5 MHz to 8.5 MHz, a viewing angle of up to 90 degrees, and a viewing depth of up to 21 cm with the ViewMate II.

2.7 Summary of Non-Clinical Testing

Bench testing was performed to confirm that the changes met design requirements and did not affect the safe or effective use of the device. The following non-clinical bench tests were performed: catheter protection, catheter inspection, tip alignment, deflection angle, tip stability, tip responsiveness, one-handed operation, planarity, handle markings, tip position and shaft-to-handle tensile test.

2.8 Summary of Design Control Activities

The development of the ViewFlex Plus ICE Catheter was performed in accordance with St. Jude Medical Quality System Requirements, and in compliance with the Quality System Regulation design controls requirements as described in 21 CFR 820.30.

2.9 Conclusion

The ViewFlex Plus ICE Catheter has the same indications for use and fundamental scientific technology as the predicate device. All technological characteristics of the ViewFlex Plus ICE Catheter are substantially equivalent to the predicate device.

Where operational and performance differences exist between the modified device and the predicate device, performance testing demonstrates that the differences do not adversely affect the safe or effective use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

St. Jude Medical
c/o Ms. Loucinda Bjorklund
Senior Regulatory Affairs Specialist
One St. Jude Medical Drive
Saint Paul, MN 55117

JUN - 2 2010

Re: K101239
Trade/Device Name: ViewFlex Plus ICE Catheter
Regulatory Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: April 30, 2010
Received: May 3, 2010

Dear Ms. Bjorklund:

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

1 Indications for Use

510(k) Number (if known): K101239

Device Name: ViewFlex™ Plus ICE Catheter, part of the ViewMate™ System

Indications for Use:

The ViewFlex™ Plus ICE Catheter, part of the ViewMate™ System, is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.

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 Cardiovascular Devices

510(k) Number K101239