ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

One St. Jude Medical Drive
St. Paul, MN 55117-9913

JAN 2 6 2011

K110085 1/2

12 510(k) Summary for Disclosure

Date Prepared: December 21, 2010

12.1 Establishment Address and Registration

St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN 55117-9913
Establishment Registration Number: 2184149

12.2 Submitter's Name/Contact Person

Kris Miller
St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN 55117-9913

12.3 Device Classification

Trade Name:	VantageView System
Common Name:	Medical cathode-ray tube display
Classification Name:	870.2450, display, cathode-ray tube, medical

12.4 Predicate Device

Cardio-View
Manufactured by: Carrot Medical-CurlView
K083321

12.5 Indications for Use

The VantageView™ System is indicated for use during electrophysiology procedures, and is intended to be used by healthcare professionals to integrate the video outputs from several commercially-available systems commonly used in a medical procedure laboratory into a single video display. Control of the video sources is accomplished using a touchpad device.

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12.6 Device Description

The VantageView System uses a 56 inch, high definition (HD), LCD display monitor that is able to integrate up to 8 video displays from up to 16 video sources. The video inputs are typically from common electrophysiology (EP) equipment used in an EP Lab (e.g., Fluoroscopy, the EP-WorkMate System, the EnSite Velocity System, MediGuide Technology, etc.). This technology creates one focused observation point for monitoring the selected displays simultaneously.

12.7 Summary of Non-Clinical Testing

SJM has conducted extensive testing of the VantageView System during development and installation.

Bench testing was performed to confirm that the product met design requirements and did not affect the safety or effectiveness of the product. The following non-clinical tests were performed: system verification testing, standard based testing, simulated clinical testing, and Instructions for Use (IFU) validation.

In addition, all electrical safety necessary to meet the IEC 60601-1 and collateral standard IEC 60601-1-1 was completed by an experienced medical device electrical testing facility.

12.8 Summary of Design Control Activities

The development of the VantageView System was performed in accordance with St. Jude Medical's Quality System requirements and in compliance with Quality System Regulations design controls requirements documented in 21 CFR 820.30.

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

St. Jude Medical
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

JAN 26 2011

Re: K110085
Trade/Device Name: Vantage View System
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode Ray Tube Display
Regulatory Class: Class II (two)
Product Code: DXJ
Dated: January 10, 2011
Received: January 11, 2011

Dear Mr. Job:

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

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MORE CONTROL LESS RISK

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St. Paul, MN 55117-9913

5 Indications for Use

510(k) Number (if known): K110085

Device Name: VantageView System

Indications for Use:

The VantageView™ System is indicated for use during electrophysiology procedures, and is intended to be used by healthcare professionals to integrate the video outputs from several commercially-available systems commonly used in a medical procedure laboratory into a single video display. Control of the video sources is accomplished using a touchpad device.

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 K110085