5.0 TRADITIONAL 510(K) SUMMARY

Submitted by: CurlView IGT, LLC
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Newton, MA 02464
Phone: 617-340-3188

Contact Person: Ward Sparacio, CEO

Summary Date: November 3, 2008

Proprietary Name: Cardio-View

Common Name: Display, Cathode-Ray, Medical

CFR Reference: 21CFR§870.2450

Class: II

Product Code: DXJ

Equivalent Marketed Device(s): Electrophysiology Systems Integrator (EPSI)
SystemsOne, LLC (K073372)

Device Description: Cardio-View is a very large screen monitor for integrating the outputs from multiple video sources onto a single display. This unit is ideally suited for training labs where physicians and medical technologists can simultaneously view the disparate systems in use in the procedure rooms for complex procedures such as electrophysiology and heart surgery.

The single display can be set up with customized views of many different procedure room activities to emphasize a particular area of interest while still providing the ability to monitor many others.

For example, the display might simultaneously show the information being provided by an anesthesiology monitoring system, an EKG monitoring system, a CAT/MRI simulator, and fluoroscope; with each optimally-positioned for the type of procedure underway.

While the display is primarily designed as an integrator and repeater of the many individual monitors typically in use in the procedure room; there is really no limit as to where it can actually be used.

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Intended Use: The Cardio-View system is intended to be used by health care professionals to integrate the video outputs from several commercially-available instruments commonly used in a medical procedure laboratory into a single video display. Control of the video sources is accomplished using a touchpad device.

Technological Characteristics: The Cardio-View system integrates multiple technologies available "off-the-shelf" from different manufacturers so they can be easily managed with less equipment. The system allows for numerous overlapping images from existing medical instrumentation to be viewed on the same large screen; records and archives data from multiple sources that are accessible on a single station and provides easy retrieval and control of all onscreen data via touchpad controls.

Substantial Equivalence Rationale: Based on an analysis of the technology and intended use of the predicate device cited, CurlView IGT, LLC, believes that the Cardio-View system is substantially equivalent to the device currently approved and on the market.

Test Conclusions: CurlView IGT, LLC, has conducted extensive testing of the Cardio-View system during development and installation. In addition, all electrical safety testing necessary to meet the IEC 60601-1 and its collateral standard IEC 60601-1-1 was completed by an experienced medical device electrical testing facility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Curlview IGT, LLC
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

NOV 2 6 2008

Re: K083321
Trade/Device Name: Cardio-View
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ
Dated: November 11, 2008
Received: November 12, 2008

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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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4.0 INDICATIONS FOR USE STATEMENT

510(k) Number: N/A

Device Name: Cardio-View

Indications For Use:

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Prescription Use: **YES**	AND/OR	Over-the-Counter Use: **NO**
(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)

for B Zuckerman

(Division Sign-Off) 11/26/08
Division of Cardiovascular Devices

510(k) Number K083321