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K101474
p1/4

## Traditional 510(k) Summary

This traditional 510(k) summary is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92:

**Date Prepared:**

March 15, 2010

**Submitter's Information: 21 CFR 807.92(a)(1)**

Perkins Healthcare Technologies
700 International Parkway
Richardson, TX 75081
Registration Number 1642869

**Contact person:**

Andrew C. Kyle
Vice President of Engineering
Tel: 877.923.4545
Fax: 214.827.6319
Email: akyle@perkins-ht.com

**Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)**

| | |
|---|---|
| **Proprietary Name:** | MD VISION System |
| **Common Name:** | Display, Cathode-Ray, Medical |
| **CFR Reference:** | 21 CFR 870.2450 |
| **Class:** | II |
| **Product Code:** | DXJ |
| **Classification Panel:** | Cardiovascular |

**Equivalent Marketed Device(s): 21 CFR 807.92(a)(3)**

**Device 1**

| | |
|---|---|
| **510(k) Number:** | K083321 |
| **Regulation Number:** | 870.2450 |
| **Device Name:** | Cardio-View |
| **Applicant:** | CurlView IGT, LLC<br>1242 Chestnut Street<br>Newton, MA 02464 |
| **Classification Product Code:** | DXJ |
| **Device Classification Name:** | Cardiovascular Monitoring Devices |

**Device 2**

| | |
|---|---|
| **510(k) Number:** | K073372 |
| **Regulation Number:** | 870.2450 |
| **Device Name:** | SystemsOne, LLC |
| **Applicant:** | SystemsOne, LLC<br>6130 Blackberry Street, Suite B<br>Anchorage, AK 99502 |
| **Classification Product Code:** | DXJ |
| **Device Classification Name:** | Cardiovascular Monitoring Devices |

**Device Description: 21 CFR 807.92(a)(4)**

The MD VISION System is a video integration system that takes the original source image from one or more devices and sends it out to a variety of locations.

- It integrates images from as many as twelve individual video sources (e.g., VGA, DVI, Coaxial, S-video, etc.)
- It processes these video inputs (e.g., by size, position, location)
- It displays up to 12 images on a Flat Panel LCD display
- A touchscreen pad controls the LCD display
- It has no patient applied parts

**Intended Use: 21 CFR 807.92(a)(5)**

The MD VISION System is intended for used by healthcare professionals to integrate the video outputs from several commercially available instruments onto a LCD display. These instruments may be commonly found in the electrophysiology laboratory, cardiac catheterization laboratory or where special or general fluoroscopy is used. The LCD display can be setup with many different customized scenes to emphasize a particular area of interest while providing the ability to monitor many others at the same time. For instance, information from an EKG monitoring system, a fluoroscopic imaging device, anesthesia monitor and an endoscope could be integrated and displayed simultaneously. The control of the scenes on the LCD display is via a touchscreen pad.

The MD VISION System is primarily designed as an integrator of the many individual displays found in use in the procedure room for training labs, procedure rooms and surgery suites. However, it really has no limit to where it could be used.

**Technological Characteristics: 21 CFR 807.92(a)(6)**

Like both predicated devices, MD VISION integrates multiple "off-the-shelf" technologies and minimizes the equipment required to meet the specific user needs. It provides easy retrieval and control of all onscreen data via a touchscreen pad.

Like the predicated device, K083321, the MD VISION system allows for numerous overlapping images from existing medical instrumentation to be viewed on the same "very large" screen, which means an 8-megapixel LCD display in its context.

In addition, like the predicated device, K073372, the MD VISION system allows for numerous overlapping images from existing medical instrumentation to be viewed on one-to-four large screens (which means a 2-megapixel LCD display) or one "very large" screen (which means an 8-megapixel LCD display monitor) in its context.

**Substantial Equivalence Rationale**

Based on the analysis of technology and intended use of the predicated devices cited, Perkins Healthcare Technologies concludes that the MD VISION System is substantially equivalent to the predicated devices currently approved and on the market.

**Performance Standard(s):**

The MD Vision System complies with applicable portions of the following product standards:

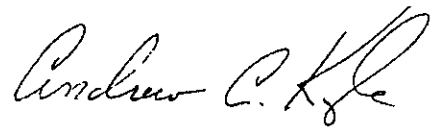
1. EN60601-1: Medical Electrical Equipment
   a. EN60601-1-4: Programmable Systems
2. UL60601-1: Medical Electrical Equipment (USA)
3. CSA C22.2#601.1-M90; Medical Electrical Equipment (Canada)
4. EN60601-1-2: EMC/EMI

**Conclusion: 21 CFR 807.92(b)(1)**

Perkins Healthcare Technologies has conducted extensive testing of the MD VISION System during development. In addition, to ensure it has meet the applicable performance standards, it has contracted with a qualified third-party Electromagnetic Compatibility Test organization (NEMKO) and a qualified third-party Medical Safety Electrical Testing Organization (INTERTEK) and obtained reports substantiating the device meets the *EN60601-1-2 Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests-Edition 2.1; EN60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety; UL60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety* harmonized to the USA National Electrical Code; *CSA C22.2#601.1-M90 Issue: 1990/01/11 (R2005) Medical Electrical Equipment – Part 1: General Requirements for Safety-General Instruction No1: Update No 2 performed in conjunction with UL60601-1.* Appropriate listing markings to demonstrate compliance are applied to production devices.

For further information or clarification of any item, please contact me.

Sincerely,



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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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Perkins Healthcare Technologies
c/o Mr. Mark Job
Responsible Third Party Reviewer
Regulatory Technologies Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K101474
Trade/Device Name: Perkins Healthcare Technologies MD VISION System
Regulatory Number: 21 CFR 870.2450
Regulation Name: Medical Display Cathode-Ray Tube
Regulatory Class: II (two)
Product Code: 74 DXJ
Dated: June 24, 2010
Received: June 25, 2010

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

K101474

# Indications for Use

510(k) Number (if known): _____

Device Name: Perkins Healthcare Technologies MD VISION System

Indications for Use:

The MD VISION System is a video integration system that takes the original source image from one or more devices and sends it out to a variety of locations.

- It integrates images from as many as twelve individual video sources (e.g., VGA, DVI, Coaxial, S-video, etc.)
- It processes these video inputs (e.g., by size, position, location)
- It displays up to 12 images on a Flat Panel LCD display
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- It has no patient applied parts

Typical users are:

- The procedure suite clinicians who need information from several sources on screen instantly showing the visual information in the way they want to see it on a large LCD display that facilitates viewing.
- Users who want to show medical procedures in real time or record medical procedures for teaching.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

W. Nosta

**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K101474