K123944
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510(K) Summary

Submitter:	Kostec Co., Ltd.
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Phone Number: **Fax Number:**	+82-33-747-9672 +82-33-747-9673
Contact Person:	Jae Kyeong, Sim
Date Summary Prepared:	20 September 2012

SEP 05 2013

Trade Name/Proprietary Name: **Models:**	Medical LCD Monitor KT-D213U5E KT-D213Q5E KT-D213V5E
Common Name/Usual Name:	System, Image Processing, Radiological (video monitor)
Classification Name:	System, Image Processing, Radiological
Product code:	LLZ
Device Class: **Regulation:**	Class II 21 CFR 892.2050
Legally Marketed Device:	LUMIMED MONOCHROME LCD MONITOR, MODELS MM 20, MM 30 AND MM50 Heeyoung Company, Ltd. K052120

Description of Device:
The Medical LCD Monitors are designed for the purpose of medical applications such as X-ray, radiology, MRI or endoscopy imaging display. The high-resolution LCD panels with a resolution of 1280x1024,

1600x1200, 2048x1536 or 2560x2048, combined with a high-performance image processing controller, provides the users extremely high-definition and high-quality medical image displays. These medical monitors comply with international EMC/ safety standards.

Indications for Use:
The Medical LCD Monitors are intended to be used in various kinds of medical image applications (excluding digital mammography) for which the device complies with the performance specifications of the system.

Comparison of Technical Characteristics:
In all material respects, the KOSTEC monitors are similar to the predicate device. Testing was performed according to internal company procedures and the monitors were safety certified to International Standards.

Though some differences between the new device and the predicate device exist, these differences do not raise new questions of safety and effectiveness.

Compliance & Voluntary Standard Compliance
The subject device has been tested against and has passed the following standards:

- IEC 60601-1:2006, General Requirements for Electrical Safety
- IEC 60601-1-2:2007, Electromagnetic Compatibility
- NEMA PS 3.1-3.18:2009 Digital Imaging and Communication (DICOM) in Medicine
- BS/EN 61000-3-2:2006+a2:2009, Electromagnetic compatibility (EMC). Liimits for harmonic current emissions
- BS/EN61000-3-3:2008, Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection

Conclusion
We have concluded that our devices are substantially equivalent to the predicate device. No new questions of safety and effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 5, 2013

Kostec Co., Ltd.
% Rhonda Alexander, MS, MPA
Senior Regulatory Specialist
Registrar Corp
144 Research Drive
HAMPTON VA 23666

Re: K123944
Trade/Device Name: Medical LCD Monitor (Models: KT-D213U5E, KT-D213Q5E and KT-D213V5E)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 26, 2013
Received: July 29, 2013

Dear Ms. Alexander:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. 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

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123944

Device Name: Medical LCD Monitor

Models: KT.D213U5E, KT.D213Q5E, KT.D213V5E

Indications for Use:

The Medical LCD Monitors are intended to be used in various kinds of medical image applications (excluding digital mammography) for which the device complies with the performance specifications of the system.

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 *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K123944