K110596 p.1 of 2

NOV 18 2011

510(k) Summary of Safety

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
February 4, 2011

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

Mr. Wongkyum Kim / CEO
WIDE Corporation
Leaders Tower Building 7FL, 456, Gomae-dong, Giheung-gu
Yongin-si, Gyeonggi-do, Republic of Korea, 446-901
Fax: +82-31-274-7400
Email: ceo@widecorp.com

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

Proprietary (Trade) Name:	MW100 (Mammography) LCD Monitor System™
Common Name:	Picture Archiving Communications System
Classification Name:	System, Image Possessing
Device Classification:	892.2050
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	system, image processing, radiological
510(k) Number	K052312
Device Name	WIDE 5MP (MAMMO) LCD MONITOR SYSTEM
Applicant	WIDE CORPORATION
Regulation Number	892.2050
Classification Product Code	LLZ
Decision Date	10/07/2005
Decision	substantially equivalent (SE)
Classification Advisory Committee	Radiology
Review Advisory Committee	Radiology
Type	Traditional
Reviewed by Third Party	No

Device Description: 21 CFR 807 92(a)(4)

The MW100 (Mammography) LCD Monitor System™ is a flat panel hi-resolution LCD monitor system for displaying medical images. The system consists of a state-of-the-art LCD monitor that connects to a hi-resolution graphic control board (not supplied by WIDE Corporation), that is installed into a PACS workstation.

The MW100 (Mammography) LCD Monitor System consists LCD monitor. The computer, computer hardware, any workstation PACS software, monitor image calibration software (e.g. Lumical Software and graphic interface is supplied by the user and should be based upon WIDE Corporation recommendations as described in the MW-100 User Manual.

Indications for Use: 21 CFR 807 92(a)(5)

The MW100 (Mammography) LCD Monitor System™ is intended to be used in displaying and viewing medical digital images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications.

510(k) Summary of Safety

Technological Characteristics: 21 CFR 807 92(a)(6)

The MW100 (Mammography) LCD Monitor System™ device is a medical image viewing system that does not contact the patient, nor does it control any life sustaining devices. Diagnosis is not performed by the monitor but by Radiologists, Clinicians and referring Physicians. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Note: The subject device does not include any automated or semi-automated process for the detection of nodules or other shapes.

Nonclinical Testing:

The complete system configuration has been assessed and tested at the factory and has passed all in-house testing criteria. The Validation Test Plan was designed to evaluate all input functions, output functions, and that as required by the risk analysis, designated individuals performed all verification and validation activities on the WIDE MW-100 device. The results demonstrated that the predetermined acceptance criteria were met. The nonclinical testing results using WIDE test plance and the requirements for monitors as outlined in AMLCD AAPM TG 18 & Specifications are provided in the 510(k).

If the device is installed by INFINITT Co., Ltd, integration and installations verification tests are conducted against acceptance criteria prior to release to the client.

Conclusion: 21 CFR 807 92(b)(1)

The Pre-Market Notification for MW100 (Mammography) LCD Monitor System™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

The subject device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. Any differences between the predicate devices and the subject device are not significant since they do not raise any new or potential safety risks to the user or patient and is equivalent in performance to existing legally marketed devices.

Nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate devices. Therefore, MW100 (Mammography) LCD Monitor System™ is substantially equivalent to the predicate device.

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

WIDE Corporation
% Mr. Carl Alletto
OTECH, Inc.
1600 Manchester Way
CORINTH TX 76210

NOV 18 2011

Re: K110596
Trade/Device Name: WIDE MW-100 Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 26, 2011
Received: September 29, 2011

Dear Mr. Alletto:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110596

Device Name: WIDE MW-100 Monitor

Indications for Use:

The MW100 (Mammography) LCD Monitor System™ is intended to be used in displaying and viewing medical digital images for review and analysis by trained medical practitioners. It is specifically designed for digital mammography applications.

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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110596