K110108

FDA CDRH DMC

JAN 14 2011

Received

Ampronix
IMAGING TECHNOLOGY

510 (K) Summary
As required by 807.92(c)

MAR 16 2011

1. Company Identification

Ampronix Inc.
15 Whatney, Irvine, Ca, 92618
Tel: (949) 273-8000
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2. Establishment Registration Number

3002816145

3. Submitter

Nelson Fathollahi
President and CEO

4. Official Correspondent

Asal Namini
Director of International Business Development
Tel: (949) 273-8000
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5. Date of Submission

January 5, 2011

6. Device Trade Name

MODALIXX G202MP

7. Common Name

LCD Monitor (Medical Equipment)

8. Device Classification

Medical Displays are classified in Class II per 21 CFR 890.2050, Picture archiving and communication system.

9. Intended Use

The MODALIXX G202MP display is intended for use by physicians and the medical industry for diagnostic imaging applications along with the Picture Archiving Communication System (PACS). The Modalixx G202MP is also intended as a direct replacement for ageing CRT medical monitors.

10. Predicate Device

Manufacturer:	Totoku Electric Co.
Device Name:	Grayscale LCD Monitor
Model Name:	Totoku ME201L/r
510(k) NO. :	K021738

11. Substantial Equivalence to Predicate Device

Modalixx G202MP is substantially equivalent to Totoku ME201L/r (K021738). They are both 20.1", 2 Mega Pixel Gray scale Modality displays.

The Modalixx G202MP has a higher contrast ratio 1500:1 compared to 1000:1 of the ME201L/r. The G202MP has a higher brightness as well to assist in a more accurate image in diagnostics by providing higher brightness and contrast ratios. The brightness improved to 1000 CD/M² from 700 CD/M² in the ME201L/r.

Comparison of the principal characteristics of the device which is a predicate to clinical performance is shown in Appendix 1(Comparison Table with Predicate Device).

12. Compliance Standards

Medical Safety:	CSA-C22.2
EMC:	UL 60601-1, CE

13. Device Description

Modalixx G202MP is a grayscale High Bright medical LCD solution for modality CRT monitor replacement. G202MP will Auto Sync to any legacy grayscale or color analog modality and up scales it to clear, sharp, and vivid high bright 2 mega pixel resolution to provide the best diagnostic medical imaging applications.

Armed with a complete set of input options, G202MP is compatible to nearly all medical modality applications. Modalixx G202MP medical LCD is capable of accepting any combination of BNC connections, including single to 5 BNC, as well as D-SUB 15. At any resolution from 525- 1600 horizontal pixels, G202MP can accept from low line to high line video signals through BNCs or VGA (D-sub15) inputs. This attribute of the Modalixx G202MP can be utilized in different types of medical imaging and application modalities as a true CRT imaging replacement.

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

Mr. Asal Namini
Director of International Business Development
Ampronix, Inc.
15 Whatney
IRVINE CA 92618

MAR 16 2011

Re: K110108
Trade/Device Name: Flat Panel LCD Monitor, Modalixx G202MP
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 5, 2011
Received: January 14, 2011

Dear Mr. Namini:

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

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

Ampronix
IMAGING TECHNOLOGY

FDA Indication for Use

510(k) Number: K110108

Device Name: Flat Panel LCD Monitor, Modalixx G202MP

Indications for Use:

The MODALIXX G202MP display is intended to be used in displaying and viewing digital images for review by trained medical practitioners before the digital images are sent to other diagnostic displays. Modalixx G202MP is not meant to be used for mammography applications.

Prescription Use ___√___ (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)

Mary S Pastel

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

510(k) K110108

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