MAR 1 2006

151

510(k): K053039

TO: Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

FROM: Randall Schroedl
Clinton Electronics Corp.

DATE: February 2, 2006

REF: **K053039**

Please find attached the information requested in your 1-26-06 follow up letter

Regards,

Randall Schroedl

K15

REF: **K053039**

Additions to Section 4.0:

4.4 Intended Use:

The Clinton Electronics Corp. DL Series II Medical Flat Panel Display are intended for use in displaying Medical Images for review by trained Medical Practitioners.

4.5 Device Description Summary:

The DL Series II Displays are Digital Monochrome LCD flat panel displays. The series II are capable of Displaying 2 mega-pixel and 3 mega-pixel formats dependent upon model type. Refer to section 5.2.1 for further details

Additions to Section 5.0

5.3 Predicated Device Equivalence:

Example #1: (3 meg format)

Regulation Number: 892.2050
510(K) number: K032638
Device Name: Dome CX Digital Flat Panel Display System Models C3 Gray
Applicant: Planar Systems, Inc,
400 Fifth Ave
Waltham, MA 02451
Product Code: LLZ
Decision Date: September 11, 2003

Example #2: (2 meg format)

Regulation Number: 892.2050
510(K) number: K042660
Device Name: NIO 2MP Medical Flat Panel Display System
Applicant: Barco NV Barcovie
12200 Academy Road NE
#931
Albuquerque, NM 87111
Product Code: LLZ
Decision Date: November 19, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2006

Mr. Randall J. Schroedl
Director of Engineering
Clinton Electronics Corp.
6701 Clinton Road
LOVES PARK IL 61111

Re: K053039
Trade/Device Name: DL series II Digital Flat-Panel Displays, Models: DL2XXX and DL3XXX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 14, 2006
Received: February 17, 2006

Dear Mr. Schroedl:

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 (Premarket Approval), 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K053039/S2

Indications for Use

510(k) Number: K053039

Device Name:

DL SERIES II DIGITAL FLAT-PANEL DISPLAYS, Models DL2XXX and DL3XXX from Clinton Electronics Corp.

Indications for Use:

The Clinton Electronics Corp. DL Series II Flat-Panel Displays are intended for use in displaying and viewing digital images by trained medical practitioners. The Displays are not intended for and should not be used for primary diagnosis in digital mammography.

Prescription Use ✓ AND/O Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) R (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053039