K040443

JUN 16 2004

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PLANAR

510(k) Summary of Safety and Effectiveness

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

Date Prepared:

January 19, 2004

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

Planar Systems, Inc.
400 Fifth Ave.
Waltham, MA 02451-8738 USA

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

Trade Name:	DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C5i™
Common Name:	Mammographic X-ray System
Classification:	892.1710
Name:	System, Image Processing

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

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K032202
Device Name	DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C5i™
Applicant	Planar Systems, Inc. 400 Fifth Ave Waltham, MA 02451-8738
Product Code	90 LLZ

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

The DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C5i™ is a flat panel hi-resolution LCD monitor system for displaying gray scale medical images for diagnostic and referral use.

The Displays use active matrix liquid-crystal display (AMLCD) panels that generate lower electro-magnetic emissions and heat, and consume less power than traditional CRT displays. The Displays use a common internal interface controller that connects directly to a common graphics display controller via a Digital Visual Interface (DVI) 1.0 interface. The Displays' Thin Film Transistors (TFTs) control transmissive liquid-crystal elements

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and use integrated Cold Cathode Fluorescent Tube (CCFT) backlight systems The DOME C5i displays five megapixels of data in a portrait or landscape orientation of 2048 x 2560 8-bit pixels. The system includes the LCD display panel, integrated drive electronics, integrated backlight, and an external power supply. Optional connections to USB can provide enhanced system functionality, including keyboard, mouse, and calibration technology.

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

The DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C5i™ is intended to be displaying and viewing radiographs of the breast for review and analysis by trained medical practitioners.

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

The device is an image display system consisting of computer software and components. The device does not contact the patient, nor does it control any life sustaining devices. A physician or trained medical practitioner provides ample opportunity for competent human intervention to interpret images and information being displayed.

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

- The new Planar, Inc. DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM, Model C5i™ is substantially equivalent to the predicate device, DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM, Model C5i™.

- The new and predicate devices are both 5Million Pixel Medical Flat Panel Display Systems intended to be used in be displaying and viewing radiographs for review and analysis by trained medical practitioners. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use. Any difference between the two devices does not affect safety or efficacy.

- The 510(k) Pre-Market Notification for the DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C5i™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate devices.

- The Planar Systems, Inc., DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C5i™ will be manufactured by in accordance with voluntary and safety standards.

- The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2004

Dome Imaging Systems, Inc.
% Mr. Ned Devine
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K040443
Trade/Device Name: DOME™ CX Digital Flat-Panel Display System™ Model C5i™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 27, 2004
Received: June 1, 2004

Dear Mr. Devine:

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 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): K040443

Device Name:
DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C5i™ from Planar Systems, Inc.

Indications For Use:

The DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C5i™ is intended to be used in displaying and viewing radiographs of the breast for review and analysis by trained medical practitioners.

Prescription Use __X___ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040443