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PLANAR

K061018

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Summary Date:	2 March 2006
21 CFR 807.92(a)(1) Submitter's Information:	Mr. Craig Harshman Planar Systems, Inc. 1195 NW Compton Drive Beaverton, OR 97006-1992 (503) 748-4661 (Phone) (503) 748-1244 (fax) craig_harshman@planar.com (Email)
21 CFR 807.92(a)(2) Device Trade Name Device common Name: Device Classification Name:	Planar Dome® EX line Model Dome® E2c SYSTEM, IMAGE PROCESSING, RADIOLOGICAL 892.2050 Picture archiving and communications system
Classification Product Code	LLZ
Establishment Registration Number:	1226517
Device Class:	Class II
Classification Advisory Committee:	Radiology
21 CFR 807.92(a)(3) Predicate Devices:	The predicate devices: 510(k) Number: **K052352** Decision Date: 09/30/2005 BARCOView, Color Coronis 2MP-21"
21 CFR 807.92(a)(4) Device Description:	The Planar Dome® EX line Model Dome® E2c is a flat panel hi-resolution AMLCD monitor system for displaying medical images. The system consists of an AMLCD monitor and a high-resolution graphic control board that connects to a PACS workstation for image display. The controller board is installed into the PACS workstation computer or other computer system used to display PACS medical images. CXtra is user-friendly software, the purpose of which is to optimize the display for DICOM-compliant viewing.
21 CFR 807.92(a)(5) Intended Use:	The Planar Dome® EX line Model Dome® E2c is intended to be used in displaying and viewing digital medical images for review, analysis, and diagnosis by trained medical practitioners. This device must not be used in primary image diagnosis in mammography.
21 CFR 807.92(a)(6) Substantial Equivalence:	The Planar Dome® EX line Model Dome® E2c is substantially equivalent to the BARCOView, Color Coronis 2MP-21" (K052352) in that: • The subsection of the system are similar in that they each consist of: o Display Monitor

- Graphic controller card installed in a PACS or PC.
- Software

- Intended use is same
- Performance attributes are similar
- Follow DICOM PS3.14 "Grayscale Standard Display Function"

21 CFR 807.92(b)
Conclusions and Statements:

This 510(k) Premarket Notification for the Planar Dome® EX line Model Dome® E2c contains adequate information and data to enable FDA CDRH to determine substantial equivalence to the predicate device.

The Planar Dome® EX line Model Dome® E2c has been tested to various Standards and was validated for its intended use.

The Planar Dome® EX line Model Dome® E2c will be manufactured in accordance with voluntary and safety standards.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 28 2006

Planar Systems, Inc.
% Mr. Marc M. Mouser
Senior Project Engineer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K061018
Trade/Device Name: Planar Dome® EX line Model Dome ® E2c
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 5, 2006
Received: April 13, 2006

Dear Mr. Mouser:

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

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PLANAR

Indications for Use

510(k) Number (if known): K061018

Device Name:

Planar Dome® EX line Model Dome® E2c
Indications for Use:

The Planar Dome® EX line Model Dome® E2c is intended to be used in displaying and viewing digital medical images for review, analysis, and diagnosis by trained medical practitioners.

This device must not be used in primary image diagnosis in mammography.

Prescription Use XX
(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 Device Evaluation (ODE)

(Posted November 13, 2003)

David A. Jogerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061018