K040555

MAY 2 6 2004

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted by:
Agfa Corporation
10 South Academy St.
Greenville, SC 29602-9048

1. **Date Prepared**
   February 25, 2004

2. **Contact Person**
   Phil Cuscuna
   Phone: (519) 746-2900 FAX: (519) 746-3745

3. **Device Name and Classification**

Trade Name:	Embrace™ Workstation
Classification Name:	Picture archiving and communications system.
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.2050
Device Class:	Class II
Device Code:	LLZ

4. **Intended Use**

   The Embrace™ Diagnostic PACS Workstation is intended for softcopy reading and diagnosis by Radiologists. It is also intended for use with regionally approved digital mammography modalities presenting processed images (DICOM "For Presentation" images) and the display of multi-modality general imaging DICOM images including adjunct breast imaging modality studies (i.e. Breast MR and Breast US).

5. **Substantial Equivalence**

   The predicate devices is General Electric Medical Systems' Seno Advantage (FDA's Clearance number: K033400; FDA's clearance date: 12/04/2003).

6. **Device Description**

   IMPAX Client Embrace™ delivers a diagnostic softcopy breast imaging workstation for the Women's Care initiative at AGFA.
   The following features are available:
   • Display of regionally approved DICOM DR Digital Mammography Images (MG SOP class)
   • Display of regionally approved DICOM CR Digital Mammography Images (CR SOP class)

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• Embrace™ product branding

The Hardware configuration of Embrace™ will consist of the following:

System (Per Host Machine):	Dell Precision™ Workstation 650; Compaq xw6000
Number & Details of CPU's	1 or 2 CPU's depending on configuration
Hard Drive space:	40GB IDE
CD-ROM:	Yes
Floppy:	Yes
Network interfaces:	System comes with an integrated 10/100/1000 Ethernet adapter
Power Supplies:	Default
Chassis:	Tower
Peripherals:	Microsoft IntelliMouse or IntelliMouse Explorer; Keyboard

Embrace™ will support the following monitors:

- BARCO Mammography MeDis 5MP CRT monitor package – MGD 521M
- BARCO Mammography 5MP and 3MP Flat Panel LCD's (EU)

7. Comparison of Technological Differences:

Technological and functional characteristics of the Agfa's Embrace™ software are identical to those of Seno Advantage. Both of these workstations allow easy selection, review, processing, filming and media interchange of multi-modality images from a variety of diagnosis imaging systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2004

Agfa Corporation
% Mr. Phil Cuscuna
Regulatory Affairs of the Americas
Agfa Health Care
455 Philip Street
Waterloo, Ontario, N2L 3X2
CANADA

Re: K040555
Trade/Device Name: IMPAX® DS3000
Client Embrace
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: February 16, 2004
Received: March 2, 2004

Dear Mr. Cuscuna:

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): K040555

Device Name: **IMPAX® DS3000 CLIENT EMBRACE**

Indications For Use:

The Embrace™ DS3000 Diagnostic PACS Workstation is intended for use with regionally approved digital mammography modalities presenting processed images (DICOM "For Presentation" images) and the display of multi-modality general imaging DICOM images including adjunct breast imaging modality studies (i.e. Breast MR and Breast US).

The Embrace™ DS3000 Diagnostic PACS Workstation when intended for diagnostic/screening Mammography viewing must do so only when used with FDA approved monitors and only when viewing Lossless format images.

The Embrace™ DS3000 Diagnostic PACS Workstation is also intended for softcopy reading and diagnosis by Radiologists.

Prescription Use ✓	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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040555