K053458

DEC 2 2 2005

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

1. **Date Prepared**
   September 14, 2005

2. **Contact Person**
   Phil Cuscuna
   Phone: (519) 572-9339 FAX: (519) 746-3745

3. **Device Name and Classification**

Trade Name:	WEB1000™
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 WEB1000™ software and the computer platform constitute a system for viewing of medical image data by trained and qualified professionals. The system is intended for use in the assembly, organization, sharing, and display of patient images and demographic information for review and referral purposes only. The WEB1000™ applet can be used for viewing images over a hospital intranet or over the Internet from a remote location. Images stored on WEB1000™ are transient, as WEB1000™ is not intended to be an archiving device.

5. **Substantial Equivalence**

The predicate device is General Electric Medical Systems' Centricity™ PACS System (Web Client Component) – a Class II device (FDA's Clearance number: K043415; FDA's clearance date: January 21, 2005)

6. **Device Description**

WEB1000™ is a software package, which may be marketed as a software only solution, as well was in conjunction with standard PC hardware. WEB1000™ is a PC-based, DICOM-compliant PACS device that is able to receive and display DICOM images. Images sent to WEB1000™ are converted into formats suitable

for viewing in a web browser, and stored in a local cache (hard disk). The algorithms used by WEB1000™ to create JPEG and wavelet images follow known and accepted protocols.

Images sent to WEB1000™ can be viewed using a Java applet that runs within a web browser such as Netscape or Internet Explorer. The WEB1000™ applet can be used for the purposes of viewing images over a hospital intranet, or over the Internet from a remote location. Images stored on WEB1000™ are transient, as WEB1000™ is not intended to be an archiving device. WEB1000™ uses standard "off-the-shelf" PC hardware and communicates using the standard TCP/IP stack. The network hardware used to support the TCP/IP stack is superfluous to WEB1000™ . WEB1000™ is intended for reference viewing of medical data. It is not for the purposes of diagnosis. Images viewed from WEB1000™ are used from reference purposes only. Diagnostic reports created from diagnostic viewing application and distributed through WEB1000™ can be used for treatment of a patient.

7. Comparison of Technological Differences:

Technological and functional characteristics of the Agfa's WEB1000™ software are identical to those of General Electric Medical Systems' Centricity™ PACS System (Web Client Component). Both of these display stations allow for the ability to display images from a number of modalities including MG (Digital Mammography) class images for nondiagnostic purposes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

AGFA Corporation
% Mr. Jeffrey D. Rongero
Senior Project Engineer
Conformity Assessment Services
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K053458
Trade/Device Name: WEB1000
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 7, 2005
Received: December 13, 2005

Dear Mr. Rongero:

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

Indications for Use

510(k) Number (if known): K053458

Device Name: WEB1000

Indications For Use:

AGFA's WEB1000 software is intended for installation on standard hardware meeting or exceeding minimum specifications. The system is intended for viewing, assembling, organizing, sharing, and displaying patient images and demographic information. The WEB1000 can be part of your evolving department solution and can also be used remotely over a hospital intranet or over the Internet.

When used by trained and qualified professionals the WEB1000 may be used for reviewing and referral purposes of medical image data collected from various types of modalities, including mammography. When used for mammography the WEB1000 should never be used as a diagnostic tool.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053458