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510K Summary
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510(k) Summary

IMPAX® Workstations with MPR, Digital Subtraction and 3D options

Common/Classifications Name: Picture Archiving and Communications System, 21 CFR 892.2050

Agfa Corporation
10 South Academy Street
Greenville SC 29602-9048
Contact: Jeff Jedlicka, Prepared July 10, 2002

A. Legally Marketed Predicate Devices

The legally marketed predicate devices are the Philips EasyVision workstations with Endo-3D option (cleared on January 8, 1998 as K973983) and Quantitative Analysis option (cleared on January 30, 1998 as K971965).

B. Device Description

The predicate devices and IMPAX® Workstations with MPR, Digital Subtraction and 3D options are medical image management devices.

Workstation configurations include a general purpose diagnostic workstation (DS3000) and analogous versions for cardiologists (Cardio3000) and orthopedists (OT3000). A review workstation (CS5000) is available for use by persons other than the interpreting physicians; and a quality control workstation (QC3000) provides administrative functions and the ability to view and correct improper operator entries.

The multi-planar reconstruction, digital subtraction and 3D features described in this notification will be offered as options, either separately or combined on multiple workstation configurations.

C. Intended Use

IMPAX® Workstations with MPR, Digital Subtraction and 3D options are intended for use in the acquisition, display, digital processing, review, transfer, storage, archiving and printing of medical images and patient demographic information.

They are indicated for use by the physician to aid in diagnosis, and by medical professionals whenever they would require or desire access to medical images and patient demographic information.

MPR and 3D functions allow the user to view 3D image data from perspectives different from that in which it was acquired. Digital subtraction allows a user viewing time series studies to remove densities not enhanced by a contrast medium, highlighting vascular structures.

D. Substantial Equivalence Summary

Impax® Workstations with MPR, Digital Subtraction and 3D options have the same intended use as the predicate devices. The differences in indications statements do not alter the intended diagnostic effect. Both the IMPAX® Workstations with MPR, Digital Subtraction and 3D, and the predicate devices are intended for use by the physician to assist in diagnosis.

The image manipulation tools are comparable. Each tool gives the user an ability to view image data from a perspective different from the one in which it was acquired.

Both IMPAX® workstations and Philips EasyVision workstation (Endo-3D, K973983) allow the user to choose optional planes from which to view three dimensional image data, and to create and view three dimensional representations.

Both IMPAX® workstations and Philips EasyVision workstation (Quantitative Analysis, K971965) allow the user viewing time series studies to remove image densities not enhanced by a contrast medium.

E. Technological Characteristics

The workstations have the same technological characteristics. All are of similar design and constructed of similar materials.

All products operate on commercially available computer systems.

All comply with the DICOM standard for communications with other imaging system components.

F. Testing

IMPAX Workstations with MPR, Digital Subtraction and 3D options are subject to testing according to established procedures by both Agfa and the software developer. No product will be released for distribution or sale until all required tests and validation activities have been successfully completed.

Tests are conducted according to documented test plans. Records of test results are maintained.

The following types of tests are conducted:

Unit tests – Tests of a single component or module, usually conducted by or

under the direction of development personnel.
System tests – Tests of multiple components or modules, up to and including the entire system. System tests are conducted by persons independent of the development personnel.
Integration tests – Tests by Agfa of system performance under simulated use conditions.
Field tests – Tests of a complete system in a user setting, but under the direct control of Agfa.
Beta tests – Tests of a system in a user setting, but without the immediate or direct control of Agfa.

G. Conclusions

This premarket notification has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2002

Agfa Corporation
HealthCare Division
% Mr. David D. Ledwig
Principal Consultant
Practical Compliance, LLC
P.O. Box 1927
BREVARD NC 28712

Re: K022292
Trade/Device Name: IMPAX® workstations with MPR, Digital Subtraction and 3D Options
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 10, 2002
Received: July 15, 2002

Dear Mr. Ledwig:

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 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 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:

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" (21 CFR Part 807.97). 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K022292

Device Name: IMPAX® Workstations with MPR, Digital Subtraction and 3D options

Indications For Use:

IMPAX® Workstations with MPR, Digital Subtraction and 3D options are intended for use in the acquisition, display, digital processing, review, transfer, storage, archiving and printing of medical images and patient demographic information.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022292

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)