K050751

APR 2 1 2005

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

1. **Date Prepared**
   February 21, 2005

2. **Contact Person**
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3. **Device Name and Classification**

Trade Name:	IMPAX® OT3000 Orthopedic Workstation
Classification Name:	PACs system. Template for Clinical Use
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.2050 21 CFR 888.4800
Device Class:	Class II
Device Code:	LLZ and HWT

4. **Intended Use**

   The Agfa IMPAX OT3000 Orthopedic Workstation is designed as an x-ray imaging system software option, which allows the planning of orthopedic surgeries on a workstation. Along with basic diagnostic display station functionality the software is intended to read in diagnostic images (e.g. digitized x-rays) for use with a database of orthopedic implant geometries and dimensions. This provides a constructed image of this data, to use in conjunction with the Agfa Impax OT3000 software to overlay the constructed images to aid surgeons in their planning of orthopedic surgeries.

5. **Substantial Equivalence**

   The IMPAX® OT3000 orthopedic component is substantially equivalent to the Siemens' EndoMap (FDA Clearance # K014113; Clearance Date: 06/14/2002).

   The Diagnostic Workstation was previously submitted for FDA approval (K022292; Clearance Date: September 12, 2002) by Agfa Corporation and (K993532; Clearance Date: December 15, 1999) by Impax Technology. The workstation component is considered here in this submission for its

integration with the OT3000 orthopedic software.

6. Device Description

Concentrating within the specialty of joint replacement, the IMPAX® OT3000 will provide an orthopedic surgeon with the ability to produce pre-surgical plans and distribute those plans for intra operative guidelines. It will also support the proper workflow necessary to effectively compare pre and post operative radiograph studies for a unique understanding of the patient's surgical outcome. Integrating this workflow with the orthopedic surgeons existing workflow and combining it with the data produced from the patient physical exam, provides a comprehensive data set for the continued prescription of a patient's relevant treatment and therapy.

The proper choice of prosthesis implant, size and placement is critical to postoperative success and minimizing intra operative complications. Proper pre-surgical planning is key for identifying the correct choices and decisions an orthopedic surgeon makes.

7. Comparison of Technological Differences:

Technological and functional characteristics of the Agfa's IMPAX® OT3000 software are identical to those of the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2005

Mr. Phil Cuscuna
Regulatory Affairs for the Americas
AGFA Corp
Healthcare
10 South Academy St.
GREENVILLE SC 29602-9048

Re: K050751
Trade/Device Name: Impax OT3000
Orthopedic Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 21, 2005
Received: March 23, 2005

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 (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

K050751

EXHIBIT 3. Indications for Use Statement

510(k) Number (if known) [redacted]

Device Name *Impax OT3000 Orthopedic Workstation*

Indications for Use

The Agfa IMPAX OT3000 Orthopedic workstation is designed to help orthopedic surgeons and specialists access images, plan surgical procedures, educate patients and monitor patient progress in a digital environment.

As an add-on component to the IMPAX client, the OT3000 orthopedic application provides digital planning to images acquired through the PACS system. These images can be utilized to place digital templates that reflect actual prosthetic implants on patients' images helping the surgeon plan the surgical placement of the implant. These plans can also be shown to patients to explain the procedure they will undergo and to help them understand the pathology present.

The application consists of an Impax Diagnostic Workstation and templates. Templates are patterns or guides intended for selecting or positioning orthopedic implants or guiding the marking of tissue before cutting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801. 109)

OR

Over-The-Counter Use_____

David B. Lyerly
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050751