K071972

L. Exhibit: 510(K) Summary

JUL 30 2007

510(k) Summary

Agfa Orthopedic Tools

Common/Classification Name: Picture Archiving and communications system (PACS), 21 CFR 892.2050
Proprietary Name: Agfa Orthopedic Software for Impax Workstations

Agfa HealthCare Corporation
10 South Academy Street
Greenville, SC 29602-9048

Contact: Tom Holbrook, Prepared: June 29, 2007
Telephone: (519) 746-6210 ext. 3297
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A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's Orthopedic Software for Impax Workstations. The predicate devices are Agfa's previous orthopedic workstation, the OT-3000 (K050751) and Cedara Software Corporation's I-SoftView Orthopedic Tools Set (K022881). The new device is nearly identical to Agfa's previous version, except for the addition of a spine-planning module. The Cedara predicate includes a spine module.

B. DEVICE DESCRIPTION

The new device is nearly identical to the Agfa predicate (OT-3000). It includes tools for performing common hip, knee and spine measurements, and provides access to orthopedic device manufacturers electronic templates. The measurements and tools enable planning of orthopedic procedures, monitoring patient progress and patient communications.

The orthopedic application is compatible with multiple workstations and Impax® software versions. User may purchase a complete set of tools or individual modules depending on their needs.

The basic principles of operation of the new and predicate devices are the same.

C. INTENDED USE

Workstations are intended for use in the acquisition, display, digital processing, review, transfer, storage, archiving and printing of medical images and patient demographic information. They allow the user to adjust image densities (window/level), perform basic length and angle measurements and highlight regions of interest. They have the ability to use 2D, 3D and time series (cine) images and data. They are intended for

use by physicians to aid in diagnosis, and by medical professionals whenever they require or desire access to medical images and patient demographic information.

The software application allows orthopedic surgeons and specialists to assess images, plan surgical procedures, monitor patient progress and educate patients in a digital environment.

It allows assessments to be made of geometrical skeletal parameters with comparisons against normative references for adults and children in order to draw therapeutic conclusions. It includes modules for the hip, knee, spine, leg, hand, wrist, elbow, shoulder, foot, ankle and fractures (trauma planning). Users can access a library of manufacturers electronic templates intended to assist in the selection and positioning of implants and the marking of tissues prior to surgery.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's Orthopedic Software for Impax Workstations have the same indications for use as the legally marketed predicate devices. It is nearly identical to the Agfa predicate (the OT-3000, K050751) except for the new spine module, which is included in the Cedara predicate (K022881).

This change in indication does not modify the intended diagnostic effect: To assist in surgical planning; monitor patient progress and communicate with the patient.

The new device has the same control methods and operating principles as the predicates. Descriptive characteristics and data provided in this submission are sufficiently precise to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are the same in the proposed and predicate devices. Users identify physiological landmarks on medical images. The software calculates commonly used measurements based on those landmarks. The software also allows the user to overlay electronic templates of orthopedic implants provided by implantable device manufacturers.

F. TESTING

Agfa's Impax® PACS Systems have been tested for compatibility with the revised orthopedic application.

Correct operation of the new spinal measurements has been confirmed with medical images in laboratory testing.

G. CONCLUSIONS

This 510(k) 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Agfa Healthcare Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUL 30 2007

Re: K071972
Trade/Device Name: Agfa Orthopedic Software for Impax® Workstations
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: July 16, 2007
Received: July 17, 2007

Dear Mr. Job:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
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): K071972

Device Name: **Agfa Orthopedic Software for Impax® Workstations**

Indications for Use:

Agfa's Orthopedic Software is indicated for use with **Impax® Workstations** in the acquisition, display, digital processing, review, transfer, storage, archiving and printing of medical images and patient demographic information. It is intended for use by physicians to aid in diagnosis, and by medical professionals whenever they require or desire access to medical images and patient demographic information.

The software application allows orthopedic surgeons and specialists to assess images, plan surgical procedures, monitor patient progress and educate patients in a digital environment.

It allows assessments to be made of geometrical skeletal parameters with comparisons against normative references for adults and children in order to draw therapeutic conclusions. It includes modules for the hip, knee, spine, leg, hand, wrist, elbow, shoulder, foot, ankle and fractures (trauma planning). Users can access a library of manufacturers electronic templates intended to assist in the selection and positioning of implants and the marking of tissues prior to surgery.

Prescription Use __X__ (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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071972