



510(k) SUMMARY

Safety and Effectiveness Information

Submitter: Apteryx, Inc.
554 White Pond Dr. Suite A
Akron, OH 44320
(330) 867-6077

Contact Person: Kevin Cruce

Date Prepared: September 2, 1998

Device Name: XrayVision

Equivalent Device: TigerView, FDA registration number 955237

Device Description

XrayVision is a software package designed to work with standard PC compatible computers capable of running Windows 95 or higher (32-bit operating systems). This software is designed to be a fully functional digital radiograph scanning, archiving, electronic transmission and diagnostic review system. *XrayVision* permits the acquisition of images directly from commercially available scanners, digital cameras, intra-oral cameras, etc. Once an image has been converted into digital form, *XrayVision* permits the user to easily organize and archive digital radiographs, images, and other patient related files to various archiving media (e.g. removable media, storage servers, hard drives, etc.). *XrayVision* provides tools that permit the user to enhance images and place markers and annotations on radiographs to aid in the diagnostic process. The image enhancements provided by this software package utilize industry standard algorithms that do not result in the alteration of an image's or a radiograph's content. Unlike a direct digital system, *XrayVision* does not control the x-ray taking system and does not generate x-ray images directly from the physical world (*XrayVision* processes images and radiographs produced from other devices and physical media). *XrayVision* only permits enhancing radiographs for diagnostic purposes and does not allow the introduction of false data or the modification of the images and radiographs in any way. To facilitate better correlation of information with images, *XrayVision* permits direct association of custom information with an image. Using these associations the user is able to relate doctor information, a patient's information, procedure, etc. with an image. When an image is transferred to another location, these associations guarantee that the correct information is always associated with an image (it is stored along with the image). Electronic transmission

capabilities are provided so that images can be sent to specialists and insurance companies for claims processing and diagnostic review. To ensure the originality and security of information, XrayVision contains security features such as digital signatures, encrypted transfers, image tracking and password protection to keep radiographs and other information safe from others and to prevent image modifications.

Intended Use

Uses for XrayVision in the dental industry are as follows:

- ◆ Permits sending of data by email, client/server, ftp, phone and floppy disk
- ◆ Organize and archive x-rays and patient related files
- ◆ Facilitate sharing and transmission of information between doctors, other applications and other computers
- ◆ Ability to place markers and annotations on x-rays for diagnostic purposes
- ◆ Allows user to take calibrated measurements
- ◆ Provide image-processing tools such as sharpening, colorizing, resizing, etc. (none of which physically alter images).
- ◆ Electronic transmission of images to insurance companies or specialist

When using XrayVision for diagnostic purposes the general public will be the doctor/dentist population. This software is primarily used to store a patient's imaging data (i.e. x-rays) in a form compatible with today's networked online practice management software. This software may also be used to transmit radiographs to specialists who will be treating the patient or the insurance company for approval of procedure and etc.

Technological Characteristics

1. Utilization of the TWAIN interface standard to acquire images from imaging devices (scanner, digital cameras and interoral cameras, etc.).
2. Utilizes standard image processing algorithms to improve image contrast, sharpness and quality.
3. Utilizes standard image file formats for the storage and retrieval of images. Primary file format uses lossless data compression (ensures data integrity). Supports JPEG (lossy) only as an import/export format.
4. Telephone: common J/O and TAPI interface supported for transferring images over conventional phone lines.
FTP: File transfer protocol.
C/S: Standard Internet transfer method for sending files via Internet client-server connection.
Email: MIMI attachments utilized to transfer files via standard Internet email.

Disk: Standard PC I/O

5. Archiving utilizes a knowledge base for recording the location used to store files related to a patient.
6. Utilizes standard markers and annotations to draw attention to problem areas in an image (ellipse, arrow, text, freehand line, dots, rectangles, etc).
7. Industry standard encryption algorithms used for ensuring data integrity.

XrayVision has the same technological characteristics as the predicate device, TigerView and TigerScan [510(k) K95-5237]. A summary of the technologies used by these devices is as follows:

End of 510(k) SUMMARY



NOV 16 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Kevin Cruscs
President
Apteryx, Inc.
554 White Pond Dr.
Suite A
Akron, OH 44320Re: K983111
X-Ray Vision (PACS)
Dated: September 4, 1998
Received: September 4, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Cruscs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K983111

Device Name: XrayVision

Indications For Use:

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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)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David G. Seymour
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K983111