K043412

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DEC 20 2004

Thursday, December 09, 2004

ViewStation, Image Management System
Premarket Notification (510(k))
510(K) Summary

Introduction

This document provides a summary of the safety and effectiveness information contained in the ViewStation Premarket Notification (510(k)). The Summary of Safety and Effectiveness contains no confidential or trade secret information and is intended for full public disclosure and distribution. For additional information, feel free to contact the submitter's Management Representative listed below.

Premarket Notification Information

1. Previous Notification Information:
    a. Previous Premarket Notification # K011694, K 942346
    b. Previous Submission Date 05/31/01, 05/16/94
    c. Previous FDA Clearance Date 08/29/01, 05/15/95
    d. Product Name ViewStation/Image RT

2. Product Information
    a. Product Name ViewStation
    b. Release Version Number Version 8.2
    c. Product Size 4.9 MB

3. Classification Information
    a. Classification Name Picture Archiving and Communications System
    b. Common/Usual Name Image Management System
    a. Product Classification Class II
    b. Product Code 90 LLZ
    c. CFR Reference 21 CFR 892.2050
    d. Review Panel Radiology

4. Establishment Information
    e. Submitter IMPAC Medical Systems, Inc.
    f. Submitter Type Manufacturer (no sterilization)
    g. Establishment Number 2950347
    h. Contact Thomas H. Faris, VP RA/QA
    i. Contact Phone 650-623-8807
    j. Contact Email TFaris@impac.com

Predicate Device

ViewStation is substantially equivalent to the original ViewStation product, which is currently marketed by IMPAC Medical Systems, Inc., and was the subject of Premarket Notifications K011694 and K942346. The new ViewStation and previous ViewStation products are equivalent in intended use and safety and effectiveness.

ViewStation Indications for Use

ViewStation supports image and information flow among health care facility personnel. ViewStation can be used whenever digital images and associated data are the means for communicating information. ViewStation is not intended for use in diagnosis.

The intended use of ViewStation is to provide health care facility personnel with an efficient and effective means to utilize patient images during the course of therapy or treatment. ViewStation allows users to import, view, annotate, manipulate, enhance, manage, and archive patient images. The images and associated information are stored in a database, providing users access to the information necessary to perform their functions.

Description of the Product

The primary function of ViewStation is to provide a means to more effectively manage image information in a therapy or treatment environment. ViewStation provides the ability to import, view, annotate, manipulate, enhance, manage, and archive patient images during the course of therapy, treatment, and follow-up.

ViewStation imports existing digital images acquired or generated by other products. ViewStation retains the original image, which was acquired or generated by a third party product. With these facts in mind, the goal of ViewStation is to make electronic patient image information more accessible throughout the department. IMPAC is providing a tool to increase department productivity since digital images, unlike films, do not have to be physically transferred from one station to another.

Summary of the Product Change

The only modifications made to the product are the following evolutionary software changes:

- Image viewing and image management feature improvements, such as improved annotation layer overlay, and image registration for calculation of relative reference position shifts.
- Privacy and security functionality to support customer HIPAA compliance.
- User interface and product registration improvements.
- Other minor workflow enhancements that do not affect product safety or efficacy.

Clinical Demonstration of Efficacy

No additional or changed diagnostic or therapeutic claims arise as the result of the change to the ViewStation product. Therefore, demonstration of clinical efficacy is not a required element of this Premarket Notification. Further, clinical performance data is not required for determination of substantial equivalence for this type and class of device.

Substantial Equivalence Comparison

ViewStation is substantially equivalent to the original ViewStation product, which is currently being marketed by IMPAC Medical Systems, Inc. This was the subject of Premarket Notifications K011694 and K942346.

This Premarket Notification is a resubmission for ViewStation, triggered by enhancement of existing functionality. A number of smaller incremental changes that are typical with routine software maintenance also accompany this change, but are too insignificant to merit discussion. The total sum of all feature enhancements does not affect the intended use of ViewStation. The technological characteristics remain principally the same. The implementation of the evolutionary product changes does not raise any new questions of safety and effectiveness, nor do the changes require novel methods of verification or validation. The product change does not diminish the safety or effectiveness of ViewStation.

The modified ViewStation Image Management System has the following similarities to the previous product that received FDA 510(k) clearance:

- Identical indications for use;
- The same operating principles;
- Incorporation of the same basic product design;
- Same materials – a software only product; and
- Sterility, biocompatibility, materials, mechanical and chemical safety, energy use, environmental compatibility, and electrical safety all remain non-applicable issues.

The sum of the changes does not affect the basic functionality of ViewStation; ViewStation remains dedicated to providing healthcare personnel with a means to import, view, annotate, manipulate, enhance, manage, and archive patient images. More simply, the changes do not affect the premise of the basic intended use of ViewStation: to provide healthcare facility personnel with an efficient and effective means to utilize patient images during the course of therapy or treatment. Once cleared by the FDA, IMPAC will continue to market and distribute ViewStation to be used in this manner.

In summary, the ViewStation Image Management System changes described in this submission are substantially equivalent to the predicate ViewStation device.

Device Safety

ViewStation is a medical device that is to be used in a treatment or therapy setting under the use of appropriately trained health care professionals who are responsible for ensuring the correct and accurate use of medical images.

The ViewStation System Hazard Analysis was performed to determine and evaluate all areas that represent potential safety or health hazards during ViewStation system operation. For all system hazards, the hazards, effects, and mitigations have all been documented (SHA2102), reviewed, and implemented. This System Hazard Analysis is reviewed with every change and release of the product, including the above-mentioned changes. Validation and verification activities trace the hazard identification and mitigation through evaluation, design, specification, implementation, and testing. The Design Review Team has reviewed the product change and System Hazard Analysis and has determined that the product change does not increase health or safety risk to patients, users, or other third parties.

Quality System

The fundamental goal of IMPAC's quality program is to provide value to customers and internal operations by producing better and safer products that are less expensive to build and maintain, simpler to use, and easier to support. IMPAC has implemented the IMPAC Quality System to operate in a manner that has proven to be the most efficient and effective. Organizational experience and expertise is built into the management system to ensure that each process consistently meets defined specifications and continuously seeks improvement. All employees receive extensive Quality System training and take pride in the value that they contribute to IMPAC products and processes and to the final customer and their patients.

ViewStation was developed according to the IMPAC Software Design Control Procedure (SDCP). This procedure governs the process by which system and software development are to be planned, defined, implemented, tested, and released.

The IMPAC Quality System was developed in compliance with all of the following standards and regulations:

DOC. ID	TITLE
ISO 9001:2000	Quality Management Systems – Requirements
ISO 13485:2003	Medical Devices – Quality Management Systems – System Requirements for Regulatory Purposes
ISO 14971:2000	Medical Devices – Application of Risk Management to Medical Devices
EN 60601-1-4 :1996	Medical Electrical Equipment – Part 1: General Requirements for Safety – 4. Collateral Standard: Programmable Electrical Medical Systems
ISO/IEC 9003 :2004	Software Engineering – Guidelines for the Application of ISO 9001:2000 to Computer Software
93/42/EEC	Medical Device Directive

Verification and Validation Testing

A Traceability Matrix has been created, based upon the project plan, to ensure the completion of the specification, implementation, and testing of all requirements of the feature enhancement, including performance of full system hazard mitigation and basic operational testing. The System Test Plan defines the overall plan for completing full application, integration, and system testing of ViewStation, while the Test Procedures capture the detailed testing parameters, results, and certification. A test certification statement certifies that the planned testing requirements were completed successfully. Design Reviews have been performed at the conclusion of each software design and development phase to review and validate the fulfillment of all of the phase requirements and deliverables. All of the above have been completed for ViewStation and representative documents are available for review.

Summary of Test Conclusions

IMPAC's Quality Engineering department has completed all product operation and hazard mitigation testing and has certified passing test results. Engineering testing was also performed to ensure that the algorithms and all other technical changes function exactly as intended. The testing demonstrated that the algorithms and all other functionality of ViewStation were successfully implemented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 2004

Mr. Thomas H. Faris
Vice President RA/QA,
Management Representative
IMPAC Medical Systems, Inc.
100 West Evelyn Avenue
MOUNTAIN VIEW CA 94041

Re: K043412
Trade/Device Name: ViewStation, Image Processing System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 9, 2004
Received: December 10, 2004

Dear Mr. Faris:

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/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

ViewStation Indications for Use Statement

510(k) Number (if known): K043412

Device Name: **ViewStation, Image Processing System**

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)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use ✓

David B. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043412