IMPAC

IMPAC Medical Systems, Inc.
www.impac.com

Corporate Office:
100 West Evelyn Avenue
Mountain View, CA 94041-1464
T 650—254 4700
F 650—428 0721

Eastern Region:
43 Thorndike Street
Cambridge, MA 02141-1764
T 617—621 2557
F 617—494 6109

Friday, July 13, 2001

K013531

QwikSIM, Virtual Simulation System
Premarket Notification (510(k))
Summary of Safety and Effectiveness

Introduction

This document summarizes the safety and effectiveness information contained within the QwikSIM 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. Product Information:
   - a. Product Name — QwikSIM Virtual Simulation System
   - b. Release Version Number — Version 2.00
2. Classification Information:
   - a. Classification Name — Radiation Therapy Simulation System
   - b. Common/Usual Name — Virtual Simulation System
   - c. Product Classification — Class II
   - d. Product Code — 90 KPQ
   - e. Reference — 21 CFR 892.5840
   - f. Review Panel — Radiology
3. Establishment Information:
   - a. Submitter — IMPAC Medical Systems, Inc.
   - b. Submitter Address — 100 West Evelyn Ave., Mountain View, CA 94041
   - c. Establishment Number — 2950347
   - d. Contact — Thomas H. Faris, Director RA/QA
   - e. Contact Phone — 650-623-8807
   - f. Contact Fax — 650-428-0721

Predicate Device Information

QwikSIM is substantially equivalent to the following devices that the Food and Drug Administration (FDA) has cleared for distribution and are currently being actively marketed in the United States. QwikSIM is substantially equivalent to these products in intended use and safety and effectiveness.

1. **Advantage Sim**

Manufacturer	General Electric Co.
Previous Premarket Notification #	K951830
Previous Submission Date	04/20/95

2. **ACQSIM Simulator/Localizer**

Manufacturer	Marconi Medical Systems
Previous Premarket Notification #	K923851
Previous Submission Date	07/31/92

3. **Somavision**

Manufacturer	Varian Assoc., Inc.
Previous Premarket Notification #	K992751
Previous Submission Date	08/16/99

QwikSIM Intended Use

QwikSIM is a radiation therapy virtual simulation system for patient image review, target and critical structure delineation, and geometric treatment planning.

QwikSIM Indications for Use

The QwikSIM Virtual Simulation System may be used by radiation oncologists, medical physicists, and medical dosimetrists for patient localization, image import and review, tumor and normal tissue delineation, and virtual simulation of treatment unit setup to support the radiotherapy treatment planning process. The resulting information may then be exported to a treatment planning system for dose calculation.

Description of the Product

The QwikSIM Virtual Simulation System provides fast and accurate visualization, contouring and beam definition tools to streamline the radiation therapy planning process. QwikSIM imports image data, and provides an array of tools for viewing and adjusting images. Manual and automatic contouring tools allow for anatomical and tumor contour definition. Beam placement and visualization tools facilitate treatment port definition, isocenter placement and laser center placement. The resulting plan data can then be used with laser positioning systems for patient marking and exported to therapy planning systems for dose calculation.

Clinical Demonstration of Efficacy

No additional or changed diagnostic or therapeutic claims arise as the result of the differences between QwikSIM and the predicate devices. Clinical performance data is not required for determination of substantial equivalence for this type and class of device.

Device Safety

The QwikSIM System Hazard Analysis was performed to determine and evaluate all areas that represent potential safety or health hazards during QwikSIM system operation. For all system hazards, the hazards, effects, and mitigations have all been documented (SHA4901), reviewed, and implemented. This System Hazard Analysis is reviewed with every change and release of the product. Validation and verification activities trace the hazard identification and mitigation through evaluation, design, specification, implementation, and testing. The QwikSIM Design Review Team has reviewed the QwikSIM System Hazard Analysis and has determined that the QwikSIM product does not pose a greater health or safety risk to patients, users, or other third parties than predicate devices listed above.

Substantial Equivalence Determination

IMPAC has determined and certified that:

A. The intended use of QwikSIM is the same as that of the predicate devices.

B. QwikSIM has the same technological characteristics as the predicate devices.

C. Any differences in the functionality of QwikSIM compared to the predicate devices do not raise any new issues of safety or effectiveness, nor are novel verification or validation methods required to assure safety and effectiveness.

QwikSIM is substantially equivalent to the previously cleared predicate devices listed above. Although functionality is not identical, the use and operation of the QwikSIM product is substantially equivalent to the predicate devices, as demonstrated by the Feature Comparison Matrix included in the Premarket Notification.

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.

QwikSIM 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
21 CFR 820	Quality System Regulation
ISO 9001:1994	Quality Systems-Model for Quality Assurance in Design, Development, Production, Installation, and Servicing
ISO 13485:1996	Quality Systems-Medical Devices-Particular Requirements for the Application of ISO 9001
93/42/EEC	Medical Device Directive
EN 46001: 1997	Application of EN ISO 9001 to the Manufacture of Medical Devices
EN 601-1-4: 1996	General Requirements for Safety

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 QwikSIM, while the Test Procedures capture the detailed testing parameters, results, and certification. The included 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 QwikSIM and representative documents have been included in the Premarket Notification.

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 QwikSIM product functions as intended and specified, according to design specifications and customer labeling. The testing demonstrated that the functionality of QwikSIM was successfully implemented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

IMPAC Medical Systems, Inc.
c/o Mr. Mark Job
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K013531
Trade/Device Name: QwikSIM Virtual Simulation System, V2.00
Regulation Number: 21 CFR §892.5840
Regulation Name: Radiation therapy simulation system
Regulatory Class: II
Product Code: 90 KPQ
Dated: October 22, 2001
Received: October 23, 2001

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 (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.

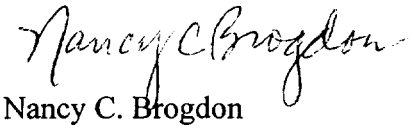
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2-1

NOV 0 7 2001

QwikSIM Indications for Use Statement

510(k) Number (if known): K013531

Device Name: QwikSIM Virtual Simulation System

Indications for Use:

The QwikSIM Virtual Simulation System may be used by radiation oncologists, medical physicists, and medical dosimetrists for patient localization, image import and review, tumor and normal tissue delineation, and virtual simulation of treatment unit setup during the treatment planning process of external beam radiotherapy treatment. This information may then be exported to a treatment planning system for dose calculation.

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013531

Prescription Use ✓