JUL 9 1998

K981313



# SEQUENCER Non-Confidential
# Summary of Safety and Effectiveness

The primary function of SEQUENCER is to assist in setting up the patient for treatment and verifying that the treatment setup is correct for a patient undergoing radiation therapy. SEQUENCER may be used to help in the setup of geometric and console parameters and verify the set parameters on the treatment machine with the planned values. After treatment the actual values can be recorded. This assists in tracking the dose given to the specified location. An intended use statement for SEQUENCER is contained in Exhibit 2a of this submission.

Normally, therapy consists of several treatment fields being delivered multiple times over a period of several weeks. Clinical studies have shown that this process is prone to random setup errors which affect treatment quality. Automatic verification of the setup values reduces the errors and the hazard to the patient. The goal of SEQUENCER is to avoid errors in setting up treatments and to properly record the actual treatment. This is accomplished by providing the user with the information necessary to completely set up the treatment machine, verifying the set values, and recording the treatment data. The recording of the actual machine parameters allows more data to be recorded and additional checks to be made.

IMPAC Medical Systems, Inc., has gained a reputation of providing high quality software products which serve the cancer therapy community. One reason we have earned this reputation is that we strive to provide end-user process oriented solutions with our products. Another reason is that software development for cancer therapy is our only business. This allows us to invoke a development system designed specifically for a cancer therapy software business. Strict adherence to these processes will ensure that SEQUENCER is a safe and effective product suitable for use as intended in a cancer therapy department.

SEQUENCER was designed and developed under the IMPAC Quality System. The IMPAC Quality System governs the processes by which system and software development are to be defined, implemented, tested, released, installed, and supported. In addition, the IMPAC Quality System demonstrates how IMPAC Medical Systems, Inc. conforms to the Quality System Regulation, 21 CFR 820, as required by the Safe Medical Devices Act of 1990.

Under the processes set forth in the IMPAC Quality System, SEQUENCER was developed per Software Requirements Specifications and documented by Software Design Descriptions. Samples of these are shown in Exhibits 4 and 5 for your review.

In addition, a Hazard Analysis was performed to determine and evaluate the areas which represent potentials hazards during SEQUENCER operation. For hazards within the scope of the SEQUENCER product, the hazard, effect, and protection implemented were documented and reviewed. The System Hazard Analysis is included in Exhibit 6.

## SEQUENCER Indications for Use Statement

SEQUENCER is to be used to facilitate the delivery of defined radiotherapy treatment plans. SEQUENCER verifies the settings on a radiotherapy treatment machine prior to treatment and records the actual parameters after treatment. SEQUENCER can be used whenever radiotherapy treatment is prescribed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 1998

Cheryl Ann Phillips
IMPAC Medical Systems, Inc.
215 Castro Street
Mountain View, CA 94041

Re: K981313
SEQUENCER (Medical Linear Accelerator)
Dated: April 8, 1998
Received: April 10, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Phillips:

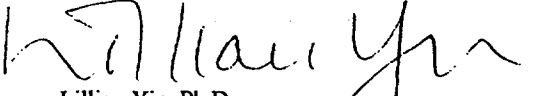
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

## SEQUENCER Indications for Use Statement

SEQUENCER is to be used to facilitate the delivery of defined radiotherapy treatment plans. SEQUENCER verifies the settings on a radiotherapy treatment machine prior to treatment and records the actual parameters after treatment. SEQUENCER can be used whenever radiotherapy treatment is prescribed.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981313

Prescription Use ✓
(Per 21 CFR 801.109)