

MAR 27 2000

**MLC Fit Non-Confidential
Summary of Safety and Effectiveness**

K991133

The primary function of MLC Fit is to provide a means to define multileaf collimator leaf plans based on a user defined shape of a desired treatment area for use with a cancer radiotherapy treatment machines equipped with multileaf collimators manufactured by Siemens Medical Systems, Varian Associates, or Elekta Oncology Systems, Inc. Users may create, view, and edit MLC leaf data as well as other geometric parameters associated with treatment field definitions. An intended use statement for MLC Fit is contained in Exhibit 2a of this submission (Exhibit 3 of the "Response").

The goal of MLC Fit is to provide the leaf positions for a given treatment shape in a manner that eliminates the slow and error prone method of hand calculating the position for each leaf and manually setting up the leaf plans. MLC Fit allows the users to define treatment field shapes and generate multileaf collimator leaf plans based on that input shape. Leaf positions and other geometric parameters can be adjusted to meet the user's clinical requirements. MLC Fit is not capable of moving the leaves or other parameters to the calculated positions. It only provides the definition of the treatment field as a hardcopy and to a database file.

The primary functions of MLC Fit are, in effect, the same as those of MLC Fit product (K962335) currently being marketed by IMPAC Medical Systems, Inc. (see Exhibit 3b). Both systems supplement the MLC treatment field definition process only, and do not attempt to control the movement of the defined parameters. The main difference is that the updated MLC Fit product has been expanded to support Elekta multileaf collimators. The user describes the characteristics of the collimator and MLC Fit uses this characterization to create the treatment definition.

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 MLC Fit is a safe and effective product suitable for use as intended in a cancer therapy department.

MLC Fit 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 Regulations, 21 CFR 820, and other applicable regulations.

Under the processes set forth in the IMPAC Quality System, MLC Fit 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 MLC Fit operation. For hazards within the scope of the MLC Fit product, the hazard, effect, and protection implemented were documented and reviewed. The System Hazard Analysis is included in Exhibit 6.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2000

Thomas Faris
Regulatory Affairs Manager
IMPAC Medical Systems, Inc.
215 Castro Street
Mountain View, CA 94041

Re: K991133
MLC Fit (Multi Leaf Collimator Planning Software)
Dated: January 18, 2000
Received: January 19, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Faris:

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 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). 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) 594-4591. 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" (21CFR 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>".

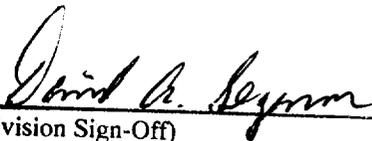
Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

MLC Fit Indications for Use Statement

MLC Fit is to be used to define leaf plans for use with radiation treatment machines equipped with multileaf collimators manufactured by Siemens Medical Systems, Varian Associates, and Elekta Oncology Systems, Inc. This method of defining the geometric parameters associated with treatment fields can be used whenever a conformal treatment field is desired.



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K991133

Prescription Use _____
(Per 21 CFR 801.109)