K973963

510 (k) SUMMARY

JAN 14 1998

MITSUBISHI LINEAR ACCELERATORS
EXL SERIES

1. Submitter:
The 510 (k) is submitted by Hideyuki Kawakami, Product Manager, Medical Systems Division, Mitsubishi Electronics America, Inc., 800 Cottontail Lane, Somerset, NJ 08873. This 510 (k) summary was prepared on October 9, 1997.

2. Device Name:
The 510 (k) submission is for Mitsubishi 120 Leaf MLC, an accessory for Mitsubishi EXL series of linear accelerators with computerized control consoles.

3. Predicate device:
The devices described in this submission are considered to be substantially equivalent to the Mitsubishi multileaf collimator.

The device is also equivalent to a multileaf collimator manufactured and distributed by Varian Associates Inc.

The predicate device are legally marketed, having been found to be substantially equivalent through the 510 (k) premarket notification process.

4. Device description:
This submission is intended to be applicable to the 120 Leaf multileaf collimator system (MLC) which can be used on Mitsubishi linear accelerators for external beam radiotherapy. The MLC system is design to provide the ability to adjust the field shape to conform to tumor shapes. It can be a substitute for conventional customer provided blocks. The MLC system consists of the collimator, the Local Control Equipment (LCE) located in the treatment room, and Multi Leaf Controller Unit (MLCU).

The collimator consists of three sets of jaws which determines the field size and shape. The top (Y-direction) jaws consist of a pair of monoblocks just like conventional accelerator therapy collimators. The middle (X-direction) jaws also consist of a pair of monoblocks. These jaws move in tandem and determine the field length.

The lower set of jaws consist of 60 pairs of leaves (120 leaves).
Each pair of leaves is independently driven by a stepping motor. Each pair of leaves can be independently set to provide irregular-shaped field settings.

5. Intended use:
The 120 Leaf MLC is indicated for use with the Mitsubishi EXL series linear accelerators to provide the ability to adjust the field shape to conform to tumor shapes. It can be a

substitute for conventional customer blocks.

6. Comparison of technological characteristics:
This submission describes the modification of existing MLC by increasing the number of leaves. Positions of leaves in both types of MLC are adjusted by motor drive mechanisms using computerized controllers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 1998

Mitsubishi Electronics America, Inc.
c/o C. L. McIntosh & Associates
12300 Twinbrook Parkway, Suite 625
Rockville, MD 20852
Attn: T. Whit Athey

Re: K973963
Mitsubishi 120 Leaf Multileaf Collimator (MLC)
for EXL Accelerator Series
Dated: October 14, 1997
Received: October 16, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Athey:

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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin

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

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K973963

Device Name:

120 Leaf Multileaf Collimator for EXL Linear Accelerator Series

Indications For Use:

The 120 Leaf MLC is indicated for use with the Mitsubishi EXL series linear accelerators to provide the ability to adjust the field shape to conform to tumor shapes. It can be a substitute for conventional customer blocks.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ONANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lagerman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973963

Prescription Use X OR Over-The-Counter Use _____