JUL 24 1998

K981112

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
as required by section 807.92(c)

1. **Submitter's Information:**

Dated March 24, 1998
Intraop Medical, Inc.
3170 De La Cruz Blvd., Suite 108
Santa Clara, CA 95054

Contact Person:

Donald A. Goer, Ph.D.
President & CEO
(408) 986-6020 (**phone**)
(408) 986-0222 (**fax**)

2. **Common or Usual Name:** Electron Linear Accelerator (Linac)
Proprietary and Trade Name of Device: MOBETRON
Device Classification: System, Radiation Therapy, Charged-Particle, Medical

3. **Predicate Device:** Siemens Mevatron ME Linear Accelerator, 510(k) Device Number K852907

4. **Description of Device:** The MOBETRON is a mobile electron beam accelerator designed specifically for use in the operating room (O.R.). Once in the OR, the accelerator head can be positioned in the horizontal plane, rotated about the coronal plane, and moved along the beam axis direction to facilitate docking with an electron applicator that is inserted into the patient. Together with the C-arm rotation, the accelerator head motion is designed to allow the accelerator to be easily and safely positioned for intraoperative treatments. All motorized motions are variable speed and are controlled by a lightweight hand-held control. The operator control system contains the dosimetry readout parameters, accelerator controls, machine interlock status, and a video output of the periscopic viewing system.

When the electrons emerge from the accelerator, they are scattered by a set of thin metallic foils and are pre-collimated to a circular field size of 10 cm. (at the standard treatment distance of 50 cm. SSD) by a primary tungsten collimator. The scattered electron beam passes through two independent transmission ion chambers and is further collimated to the desired field size by electron applicators which are inserted into the patient. The scattering foil and collimation technique and applicator systems used in the Mobetron is similar to techniques used for IORT in other electron accelerator systems. The Mobetron provides four (4) electron beams of energy 4, 6, 9 and 12 MeV, and a set of electron applicators of various diameters from 3 cm to 10 cm to enable the delivery of Intraoperative Radiotherapy (IORT) treatment.

5. **Statement of Intended Use:** The Mobetron is a mobile electron linear accelerator that produces beams of electrons used in the radiation therapy treatment of both malignant (cancer) and benign conditions. The Mobetron has four electron beam treatment energies and a set of electron applicators which provide a range of field sizes from 3 to 10 cm in diameter.

For delivery of electron beam radiation during a surgical procedure, known as Intraoperative Radiation Therapy (IORT), the Mobetron system includes a sterile cap and sterile drapes for each IORT procedure, IORT applicators, a QA system, a surgical table extender with added support leg, and bolus material.

The intended use is the same as the predicate device.

6. **Statement of Technological Characteristics:** The basic operation of the Mobetron is similar to that of any electron linear accelerator system, in that it employs a modulator, electron gun, rf-system and accelerator guide system. In the Mobetron, a lightweight electron beam linear accelerator is mounted on a motor driven gantry. The gantry is attached to a stand which is supported on a self-contained transportation system. A modulator and operator control console complete the system. This system produces electron beams of energies, field size, and dose rate equivalent to other electron accelerators used for IORT.

The intended use and performance characteristics are equivalent to the predicate device and therefore we believe it is substantially equivalent to it.

7. **Differences:** The differences between the systems are minor and do not effect the safety and efficacy of the treatment. The major difference between the Mobetron and the predicate device is that the predicate device is fixed in location and limited to a single O.R. The Mobetron is mobile and can be used in more than one O.R. Once it is in a specific O.R., its use is essentially identical to the predicate device. To assure that the Mobetron is performing correctly after it is moved to a new location, output and energy checks are made using a quality assurance device provided with the unit. The predicate device requires similar testing of output and energy prior to use even though the device is not moved. The Mobetron is thus substantially equivalent to the predicate device.

8. **Performance Evaluation:** Performance tests were conducted and the results indicated that the Mobetron consistently performed within the design parameters and equivalently to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 1998

Donald A. Goer, Ph.D.
President
Intraop Medical
3170 De La Cruz Blvd., Suite 108
Santa Clara, CA 95054

Re: K981112
Mobetron (Electron Linear Accelerators)
Dated: March 24, 1998
Received: March 26, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 LHN

Dear Dr. Goer:

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

STATEMENT OF INDICATIONS FOR USE

The Mobetron is a mobile electron linear accelerator that produces beams of electrons used in the radiation therapy treatment of both malignant (cancer) and benign conditions. The Mobetron has four electron beam treatment energies and a set of electron applicators which provide a range of field sizes from 3 to 10 cm in diameter.

For delivery of electron beam radiation during a surgical procedure, known as Intraoperative Radiation Therapy (IORT), the Mobetron system includes a sterile cap and sterile drapes for each IORT procedure, IORT applicators, a QA system, a surgical table extender with added support leg, and bolus material.

David A. Seymm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981112

Prescription Use ✓
(Per 21 CFR 801.109)