HITESYS

JUN 2 2 2000

K990209
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510(k) Summary of Safety and Effectiveness as required by 21 CFR 807.92(c)

1. Submitter's Information:

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Date Summary Prepared: 12 January 1999

2. Device Name:

Common or Usual Name:	Electron linear accelerator (Linac)
Proprietary and Trade Name:	NOVAC7
Classification Name:	Radiation Therapy, Charged-Particle, Medical System per 21 CFR 892.5050

3. Predicate Device: MOBETRON, 510(k) number K981112
Intraop Medical Inc.
Santa Clara, CA 95054

4. Description of Device:

The NOVAC7 is an electron accelerator for intraoperative radiation therapy that can be used in the operating room without making major adjustments to the room. Beam energies are 3, 5, 7, and 9 MeV. It is a mobile, hinged accelerator that can be moved to the patient's location and placed in the appropriate position for performing the required radiotherapy inside a surgical theatre. X-ray leakage into the environment and other related radiation protection problems have been minimized by eliminating diffusion filters which in conventional accelerators widen the beam.

Hard docking is performed in an easy way, reaching any site of the body. Two applicators are used, one is located over the patient area to be treated and the other is permanently mounted on the radiating head. Only the patient applicator comes in contact with the surgery site. The time required for performing docking and scanning irradiation is under five minutes.

5. Statement of Intended Use:

The NOVAC7 is an electron linear accelerator used for radiation therapy during surgical procedures in an operating room for the treatment of malignant and benign conditions. Know as intraoperative radiation therapy (IORT), this technique allows delivery of high doses of radiation directly aimed at tumors or other sites while avoiding dosage to surgically mobilized normal tissues.

The NOVAC7 is a mobile and articulated machine that can be moved towards the patient and put in the appropriate position to carry out the necessary radiotherapy. Applicators direct the electron beam to the surgical area of interest.

The intended use is the same as the predicate device.

6. Comparison with Predicate Device:

The NOVAC7 and the Mobetron differ in their accelerating structures. The NOVAC7 uses a simple and singular stationary wave structure in which the energy is varied by changing the level of peak power of the magnetron. On the other hand, the Mobetron is based on a collinear structure that is more complex and varies the energy by changing the phase of the power supply of the second structure. The NOVAC7 uses a normal accelerating magnetron in the S band, well known to radiotherapy departments worldwide. The Mobetron uses X band.

The Mobetron has significant attenuation of the electron beam by the use of a scattering filter. This approach provides a dose rate that is easily measured and the possibility of using very short applicators (50 cm). However, as a result, the machine must be heavily shielded and provided with a primary collimator to maintain acceptable levels of diffused radiation. In contrast, the NOVAC7 uses a beam produced by the accelerator without an intermediate structure. This means that longer applicators (80 - 100 cm) must be used and that the measurement of the instantaneous dose requires integrated dosimetry. However, this keeps the weight of the machine down and its diffused radiation to very low levels.

The Mobetron uses soft docking because of the high inertia and weight of the mobile parts of the machine. The radiating head of the NOVAC7 weighs less than 50 Kg and is moved very smoothly by electric motors that in no way allow pressure on the patient. Therefore, hard docking was used. This system ensures excellent mechanical repeatability and therefore an ideal uniformity of the field. The Mobetron requires that the patient always be moved toward the accelerator whereas the NOVAC7 does not require any movement of the patient. The machine is moved by its motors by means of a remote control unit to the operating field and therefore does not require any logistics beyond those usually required during surgery.

In spite of these differences, when considering the requirements of section 510(k) of the Federal Food Drug and Cosmetic Act, the two systems are substantially equivalent based on features such as the use of electron beams for intraoperative radiation therapy, the beam energies, and mobility within the surgical suite.

7. Performance Evaluation:

The NOVAC7 has been designed and tested for electrical patient safety by conforming to applicable portions of IEC 60601-1, 60601-1-1, 60601-1-2, 60601-1-4, and 60601-2-1. The software is developed in accordance with a software development program plan and the software level of concern, as described in the document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 29, 1998.

9. Conclusion:

Based on the analysis of the comparison in item 6 above and the performance evaluation results contained in item 7, Hitesys S.p.A. has concluded that the NOVAC7 is safe, effective, and performs as well as or better than the legally marketed device identified in item 3 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2000

Pompilio Gatto
Managing Director
Hitesys S.p.A.
Via dell'Industria, 1/A
04011 Aprilia
Italy

Re: K990209
Hitesys NOVAC7 Linear Accelerator
Dated: May 1, 2000
Received: May 1, 2000
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Gatto:

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)

HITESYS

Statement of Indications for Use

510(k) Number (if known): To be assigned

Device Name: NOVAC7

The NOVAC7 is an electron linear accelerator used for radiation therapy during surgical procedures in an operating room for the treatment of malignant and benign conditions. Know as intraoperative radiation therapy (IORT), this technique allow delivery of high doses of radiation directly aimed at tumors or other sites while avoiding dosage to surgically mobilized normal tissues.

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Concurrence of CDRH
Office of Device Evaluation
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

Prescription Use __/__ OR Over-The-Counter Use ____
(Per 21CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990209