

JUL 20 2001

K983332

**510(k) SUMMARY**  
**Massachusetts General Hospital**  
**Northeast Proton Therapy Center**

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

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Contact Person: same as above

Date Prepared: September 21, 1998

**Name of Device and Name/Address of Sponsor**

Northeast Proton Therapy Center

Massachusetts General Hospital  
Northeast Proton Therapy Center  
30 Fruit Street  
Boston, MA 02114

**Classification Name**

Medical Charged-Particle Radiation Therapy System (21 C.F.R. § 892.5050)

**Predicate Devices**

- (1) Loma Linda University Medical Center's Proton Beam Therapy Center (K872369)
- (2) Harvard University Cyclotron Laboratory's Proton Beam Therapy Center (preamendments device)

**Intended Use**

The Northeast Proton Therapy Center ("NPTC") is a facility designed to produce and deliver a proton beam of known energy, intensity and shape for treatment of a patient. It is indicated for use in the therapeutic application of a

proton beam for the treatment of localized tumors or other diseases that are susceptible to treatment by radiation. The facility is designed so that it will: (1) create and direct (deliver) the proton beam appropriately to the patient treatment location; (2) produce a transverse and longitudinal dose distribution appropriate for the patient treatment; and (3) deliver the designated dose to the patient's treatment site.

### **Technological Characteristics**

The equipment installed in the NPTC is comprised of the following two main components: (1) the beam delivery equipment and (2) the beam production equipment. The primary responsibility of the beam delivery equipment is to direct the proton beam to the patient's treatment site within the patient treatment location and to ensure that the patient critical functions are properly and safely carried out. The beam production equipment is necessary to produce the proton beam and direct it to the appropriate treatment room. In addition to the main components, the equipment in the NPTC also includes: (1) a Therapy Safety System ("TSS"); and (2) a computer-based Therapy Control System ("TCS").

### **Substantial Equivalence Discussion**

The NPTC is substantially equivalent to both the Loma Linda (K872369) and the Harvard Cyclotron Laboratory proton therapy devices, the latter of which is a preamendments device. Like its predicate devices, the NPTC is a facility designed to produce and deliver a proton beam of known energy, intensity and shape for treatment of a patient. It is indicated for use in the therapeutic application of a proton beam for the treatment of localized tumors or other diseases that are susceptible to treatment by radiation.

The NPTC and its predicate devices provide the same or substantially equivalent functions, characteristics, and accessories as the NPTC. All of these devices are comprised of beam delivery systems that shape, direct, and monitor the protons delivered to the patient. They are also comprised of beam production equipment that generates the beam used by the beam delivery systems. All of the facilities include patient treatment rooms, but each has a different number of rooms.

The beam range in both the NPTC and Loma Linda facilities is similar. Even though the NPTC and its predicate devices use different accelerators, the engineering principles underlying their design are the same. The safety and control systems for the NPTC, Loma Linda, and HCL facilities are equivalent.

Although there are some differences between the NPTC and its predicate devices, these differences are minor and raise no new questions of safety and effectiveness.

## **Performance Data**

The submission includes performance testing that Massachusetts General Hospital conducted to demonstrate that the device meets its performance specifications.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Massachusetts General Hospital  
% Mr. Jonathan S. Kahan  
Hogan & Hartson, L.L.P.  
Columbia Square  
555 Thirteenth Street, NW  
WASHINGTON DC 20004-1109

Re: K983332  
Northeast Proton Therapy Center (Proton Therapy Center)  
Dated: June 4, 2001  
Received: June 5, 2001  
Regulatory Class: II  
21 CFR 892.5050/Procode: 90 LHN

Dear Mr. Kahan:

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) 594-4639. 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,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K983332

Device Name:

Northeast Proton Therapy Center

Indications for Use:

The NPTC is a facility intended to produce and deliver a proton beam of known energy, intensity and shape for treatment of a patient. It is indicated for use in the therapeutic application of a proton beam for the treatment of localized tumors or other diseases that are susceptible to treatment by radiation. The facility is designed so that it will: (1) create and direct (deliver) the proton beam appropriately to the patient treatment location; (2) produce a transverse and longitudinal dose distribution appropriate for the patient treatment; and (3) deliver the designated dose to the patient's treatment site.

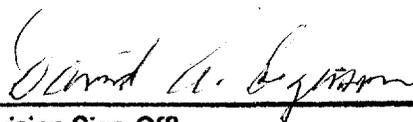
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Concurrence of CDRH, Office of Device Evaluations (ODE)

Prescription Use  OR Over-the-Counter Use

(Per 21 C.F.R. 801.109)  
(Optional Format 1-2-96)



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K983332