

JUL 21 2000

510(k) SUMMARY  
For  
OPTIVUS PROTON BEAM THERAPY SYSTEM

K992414  
Page 143

1. COMPANY NAME/ADDRESS

1.1 Sponsor Contact

Optivus Technology, Inc.  
P.O. Box 608  
Loma Linda, CA 92354  
Contact Person: Clark Taylor  
Telephone: (909) 799-8300

1.2 Sponsor Manufacturing Address

Optivus Technology, Inc.  
1475 South Victoria Court  
San Bernardino, CA 92408

Date Prepared: July 19, 1999

2. DEVICE NAME

Proprietary Name: Proton Beam Therapy System (PBTS)  
Common/Usual Name: Proton Beam Therapy System  
Classification Name: Medical Charged-Particle Radiation Therapy System

3. PREDICATE DEVICES

The Optivus Proton Beam Therapy System (PBTS) is substantially equivalent to the Loma Linda University Medical Center (LLUMC) PBTS. The LLUMC PBTS was cleared for marketing in the United States in the premarket notification, K872369.

**4. DEVICE DESCRIPTION**

The Optivus Proton Beam Therapy System (PBTS) is an integrated facility designed to deliver radiation treatment. Optivus' proposed facility is essentially the same as the facility that is currently operating at LLUMC. Both facilities consists of three major functional blocks; the accelerator, the beam transport system, and the treatment rooms. This complete, turnkey system consists of seven major subsystems:

- 70 - 250 MeV proton synchrotron;
- beam transport system;
- one or more fixed beam delivery systems;
- one or more isocentric gantries;
- patient positioning system;
- integrated facility control system; and
- integrated facility safety system.

**5. INTENDED USE**

The Optivus Proton Beam Therapy System (PBTS) is an integrated facility designed to administer proton radiation treatments to patients through delivery of a predetermined radiation dose to a predetermined treatment target volume in a manner that protects people from unnecessary exposure to radiation and other hazards. This is the same intended use as the LLUMC PBTS.

**6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE**

The Optivus PBTS has the same technological characteristics as the LLUMC PBTS. The comparison matrix for the LLUMC PBTS and the Optivus PBTS is summarized below.

Table 1: Comparison matrix between the Optivus PBTS and the Loma Linda University Medical Center PBTS

K992414  
Page 3 of 3

Characteristic	LLUMC PBTS	Optivus PBTS
Accelerator	Synchrotron, approx. 20 ft. diameter	Same as LLUMC PBTS
Particle	Protons	Same as LLUMC PBTS
Energy	Continuously variable from 70-250 MeV, corresponding to a water depth of 3 cm to 38 cm.	Same as LLUMC PBTS
Total Cycle Time	2 seconds nominal	1.5-10.0 seconds (2.2 sec nominal)
Spill Time	1 second	0.1-9.0 seconds (0.5 sec nominal)
Cycle Completion Time	0.5 seconds	0.1-9.0 second (1 sec nominal)
Beam Intensity	$> 1.5 \times 10^{11}$ protons per pulse	A variable beam intensity in ten steps over range ( $1 \times 10^{19}$ to $3 \times 10^{10}$ protons per pulse).
Proton Source	40 keV duoplasmatron	40 keV duoplasmatron (nominal)
Injector Type	Radio Frequency Quadrupole	Same as LLUMC PBTS
Injection Energy	1.7 MeV	2 MeV (nominal)
Treatment Facilities	3 treatment rooms with isocentric gantries, one treatment room with fixed horizontal beam, and a fixed-beam dedicated to calibration and non-patient use.	At least one isocentric gantry treatment room and one fixed-beam treatment room.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 21 2000

Optivus, Inc.  
c/o James R. Veale  
Vice President, Regulatory Services  
Medical Device Consultants, Inc.  
49 Plain Street  
North Attleboro, MA 02760

Re: K992414  
Optivus Proton Beam Therapy System (PBTS)  
Dated: April 28, 2000  
Received: May 1, 2000  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 LHN

Dear Mr. Veale:

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)

510(k) Number (if known): K992414

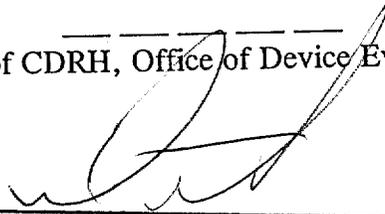
Device Name: Proton Beam Therapy System

Indications for Use:

The Optivus Technology, Inc.'s Proton Beam Therapy System (PBTS) is an integrated facility designed to administer proton radiation treatments to patients through delivery of a predetermined radiation dose to a predetermined treatment target volume in a manner that protects the patient from unnecessary exposure to radiation and other hazards.

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K992414

Prescription Use    
(Per 21 CFR 801.109)

OR

Over-The-Counter Use