



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

McLaren Health Care Corporation  
% Daniel Gottlieb, Esq.  
Attorney  
Epstein Becker & Green, P.C.  
1227 25<sup>th</sup> Street NW, Suite 700  
WASHINGTON DC 20037

February 25, 2016

Re: K160063  
Trade/Device Name: McLaren Proton Therapy System  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: LHN  
Dated: January 11, 2016  
Received: January 13, 2016

Dear Mr. Gottlieb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the printed name and title.

For

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160063

Device Name

McLaren Proton Therapy System

Indications for Use (Describe)

The McLaren Proton Therapy System is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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**510(k) Summary**  
**McLaren Proton Therapy System**

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

Epstein Becker Green  
1227 25<sup>th</sup> St. NW Ste. 700  
Washington, DC 20037

Telephone: 202-861-1881  
Facsimile: 202-861-3581

Contact Person: Daniel Gottlieb  
Date Prepared: January 11, 2016

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

McLaren Proton Therapy System

McLaren Health Care Corporation  
G-3235 Beecher Rd., Suite B  
Flint, MI 48532

**Common or Usual Name**

Proton beam therapy systems

**Classification Name**

Medical Charged-Particle Radiation Therapy System, 21 CFR 892.5050, Product Code LHN

**Predicate Device**

ProTom Radiance 330<sup>TM</sup> Proton Beam Therapy System (K134052)  
Cleared Mar 14, 2014

**Intended Use**

The McLaren Proton Therapy System is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

## 510(k) Summary

### McLaren Proton Therapy System

#### Technological Characteristics

The McLaren Proton Therapy System consists primarily of Beam Delivery and Beam Production systems. These systems are comprised of various components and/or accessories designed to produce and deliver a proton beam appropriate for patient treatment. The system components include:

- Beam Production System. This system produces the proton beam and directs it to the appropriate treatment room and is comprised of the following subsystems:
  - Synchrotron subsystem. The accelerator unit is the source of the proton beam and is composed of the injector (which generates the proton beam) and the synchrotron (which accumulates, accelerates, and extracts the proton beam).
  - Beam Transport subsystem. This subsystem guides the proton beam extracted from the synchrotron to the treatment room.
- Beam Delivery System. This system controls the irradiation dose and shapes the proton beam supplied through the beam transportation system into the configuration required for patient treatment, and directs the beam appropriately. It is comprised of the following subsystems:
  - Scan/Dose subsystem
  - Gantry subsystem
  - Patient Positioning subsystem.
  - Treatment Delivery Control subsystem

#### Performance Data

Each individual subsystem of the McLaren Proton Therapy System was verified and validated, and full system verification and validation was also performed. Beam performance testing to validate complete system integration under nominal and non-nominal conditions was performed on the full system. Beam delivery testing evaluated the following:

1. Creation and direction the proton beam appropriately to the patient treatment location;
2. Production of a transverse and longitudinal distribution appropriate for the patient treatment; and
3. Delivery of the designated dose to the patient's treatment site.

Testing to evaluate electrical safety and electromagnetic compatibility was performed in accordance with IEC 60601-1 and IEC 60601-1-2, and a usability evaluation was conducted to confirm that users can interact with the system user interface to perform treatment with the device system.

All testing demonstrated that the system met its specifications for its intended use.

#### Substantial Equivalence

Except for the device name, the McLaren Proton Therapy System has the identical intended use, indications, principles of operation, and technological characteristics as the ProTom Radiance 330™ Proton Beam Therapy System (K134052).

## **510(k) Summary**

### **McLaren Proton Therapy System**

The McLaren Proton Therapy System is identical to the ProTom Radiance 330™ Proton Beam Therapy System and there are no new questions of safety or effectiveness.

Thus, the McLaren Proton Therapy System is substantially equivalent to its predicate device.