K131150
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510(K) Summary

Cura Medical Technologies LLC
23 Rancho Circle
Lake Forest, CA 92630
949-716-2447
www.curamedtech.com

April 17, 2013

JUL 3 0 2013

Range Compensator, Radiation Beam Shaping Device
Premarket Notification (510(k)) Summary,
as required by 21 CFR 807.92(c)

Introduction

This document provides a summary of the safety and effectiveness information contained in the Cura Compensator Premarket Notification (510(k)). This Premarket Notification (510(k)) Summary contains no confidential or trade secret information and is intended for full public disclosure and distribution. For addition information, please contact the Establishment's contact listed below, Thomas H. Faris.

Premarket Notification Information

Previous Notificaton Information:

Previous Submission #:	None, Initial Submission
Previous FDA Clearance Date	None
Product Name	Cura Compensator

Submitter's Information :

Cura Medical Technologies
23 Rancho Circle
Lake Forest, CA 92630

Contact Person:

Thomas Faris
Regulatory Counsel
C/O Mevion Medical Systems, Inc.
300 Foster Street
Littleton, MA 01460
Phone: 650-996-1192
Email: thomfaris@yahoo.com

Trade Name: Cura Compensator

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Classification Information:

Classification Name	Custom Beam Block
Proudct Code	IX1
CFR Reference	21 CFR892.5710
Product Classification	Class II
Review Panel	Office of In Vitro Diagnostic Device Evaluation and Safety

Predicate Device:

.decimal Range Compensator
K071078

Proton Systems
Proton radiation therapy beam-shaping aperture and range compensator
K121657

Intended Use/Indications for use

The Cura Compensator is a solid, machine-shaped acrylic or wax block intended to attenuate external radiation beam and block radiation from hitting critical structures and healthy tissue while allowing the radiation dose to the targeted area. The Cura Compensator may be used as an accessory whenever external beam radiation therapy is indicated for the treatment of patients with localized tumors or other conditions susceptible to treatment by radiation.

Summary Device Description

Cura Compensators are custom beam blocks with machined cutout to allow beam passage per prescription and sized to snugly fit the applicator or nozzle and block all remaining beam in the radiation therapy fraction delivery. The Compensator is made of acrylic or wax with notch orientation to match radiation machine manufacturer use specifications. No software is included in this device.

Summary of Technological Characteristics

Cura Compensators, sometimes also called range compensators, are made of acrylic, custom cut to hospital users' specifications, and used for external beam radiation therapy treatments. The acrylic compensator cutouts are designed according to the Treatment Plan parameters designated by hospital personnel and then transmitted to Cura machining centers for custom manufacture and delivery back to the hospital.

The device features of Cura Compensators are similar to the predicate device, .decimal Tissue Compensator/Intensity Modulator. They both are made of acrylic, custom cut to hospital users'

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specifications, and used for external beam radiation therapy treatments. They both are used to block radiation and guide it to affected areas. The target population is identical and the use parameters are also very similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2013

Cura Medical Technologies, LLC
% Mr. Thomas H. Faris
Regulatory Counsel
23 Rancho Circle
LAKE FOREST CA 92630

Re: K131150
Trade/Device Name: Cura Compensator
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: IXJ
Dated: April 17, 2013
Received: May 7, 2013

Dear Mr. Faris:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Michael D. O'Hara for

Janine M. Morris
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): K131150

Device Name: Cura Range Compensator

Indications for Use:

The Cura Compensator is a solid, machine-shaped acrylic block intended to attenuate external radiation beam and block radiation from hitting critical structures and healthy tissue while allowing the radiation dose to the targeted area. The Cura Compensator may be used as an accessory whenever external beam radiation therapy is indicated for the treatment of patients with localized tumors or other conditions susceptible to treatment by radiation.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K131150