K010062

MAR 1 3 2001

arplay medical

Premarket Notification [510(k)] Summary
Tab 4

radiothérapie
radiotherapy
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curiethérapie
brachytherapy
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radioprotection

December 22, 2000

Trade Name: Styrofoam Cutters for Block Casting System

Common Name: Beam Shaping Block Cutter

Classification Name: Block, Beam-Shaping, Radiation Therapy, 90 IYI (per 21 CFR section 892.5710)

Manufacturer's Name: Arplay Medical S.A.
Address: 1 Route de Citeaux
21110 Izeure
France

Corresponding Official: Richard Borgi, MD
Title: President and CEO
Telephone: +33-3-8029 7401
Fax: +33-3-8029 7622

Predicate: Diacor Inc., Portalcast, K860193

Device Description: The purpose of the Styrofoam Cutter is to enable the treatment staff to fabricate beam-defining blocks that will fulfill the prescription of the Radiation Oncologist.

For photon treatments, the Styrofoam Cutter consists of a light box table for x-ray films and a tall vertical mount on the rear. Two horizontal arms are attached to the mount and are adjustable in the vertical direction. The upper arm has a gimbal mount suspending a vertical rod that reaches to the upper surface of the light box. The gimbal simulates the treatment machine radiation source for any model of linear accelerator or Cobalt-60 machine. Its height, and the length of the rod, is adjustable to replicate the distance from the source to the position of the x-ray film when the exposure was made.

The lower arm is adjusted to the source to beam defining tray position of the specific treatment machine. This arm contains a mount for the styrofoam block. The vertical rod is interrupted at this point by a "D" shaped portion that supports a cutting wire and rigidly connects the upper and lower portions of the rod. The cutting wire is resistive and is heated by a voltage source. As the free end of the rod is traced over the beam defining lines drawn on the x-ray film by the Radiation Oncologist; the hot wire "cuts" the styrofoam.

After the cut out Styrofoam is removed, a low melting point lead alloy (Cerrobend) is poured into the cavity and cooled to form the beam defining blocks. The blocks are attached to a transparent plastic tray for use on the treatment machine.

When the verification option is purchased, the plastic tray with the beam blocks is placed back in position on the lower arm of the Styrofoam Cutter. The gimbal mount slides forward and a light slides into the position of the source. This light casts a shadow of the blocks on the x-ray film and allows the operator to observe that the blocks do conform to the physician's prescription. If they do not, adjustments are made until confirmation occurs.

Since the beam defining blocks for electron treatments are much thinner and nearly in contact with the patient, a simpler form of styrofoam cutter is available. It consists only of a table with a "C" arm with a wire stretched between the "C" and a table top. A simple paper template drawn by the Radiation Oncologist is placed on top of the styrofoam and moved around the wire to form the template for the low melting point lead alloy block.

Intended Use: The Styrofoam Cutters are intended for use in cutting styrofoam in order to produce molds for casting low melting point lead alloy beam defining blocks used in external beam radiation therapy.

Technological Characteristics: Predicate Comparison Table

#	Feature	Portalcast, K860193	Arplay Medical Styrofoam Cutters
1	Source to film distance	Adjustable	Photon: Adjustable Electron: Fixed
2	Source to tray distance	Adjustable	Photon: Adjustable Electron: Fixed
3	Hot wire cutter	Yes	Yes
4	Cutting wire aligned with beam divergence	Yes	Photon: Yes Electron: Vertical
5	Source simulator light	Yes, checks block alignment on tray	Photon: Yes, checks block alignment on tray
6	Light box for X-ray film	Yes	Photon: Yes Electron: No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2001

Richard Borgi, M.D.
President & CEO
Arplay Medical S.A.
1 Route de Citeaux
21110 Izeure
FRANCE

Re: K010062
Styrofoam Cutters for Block Casting Systems
Beam Shaping Block Cutter
Dated: December 22, 2000
Received: January 8, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Dr. Borgi:

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,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Tab 3

Indications For Use

510(k) Number: K010062

Device Name: Styrofoam Cutters for Block Casting System

Indications for Use:
To cut styrofoam in order to produce molds for casting low melting point lead alloy beam defining blocks used in external beam radiation therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010062

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)