510(k) Summary

ART Breast Brachytherapy Applicator

JUN - 6 2006

1. Sponsor Name

Advanced Radiation Therapy, LLC
9 Linnell Circle, Billerica, MA 01821
Telephone: 978-663-7300
Fax 978-663-7322
Contact Individual: Raymond J. Bricault Jr., Chief Operating Officer

2. Device Name

ART Breast Brachytherapy Applicator

3. Identification of Predicate or Legally Marketed Device

Mick Nuclear - HAM Applicator - K961601
Nucletron Freiburg Flap Applicator set - K983338
Varian Medical Systems - Catheter Flap – 510(k) unknown but currently advertised and believed to be legally marketed

4. Device Description

The Advanced Radiation Therapy (ART) Breast Brachytherapy Applicator is a rigid applicator used for non-invasive HDR treatment of the breast. The applicator is designed to be positioned external to the breast to receive the HDR afterloader source via catheter lumens. The position and placement of the applicator is verified by means of radiographic images and the travel distance of the HDR source in the lumens is determined radiographically by using the check cable of the afterloader equipment. With the applicator properly immobilized on the breast surface, the HDR treatment process can begin according to established protocols.

5. Intended Use

The ART Breast Brachytherapy Applicator is a rigid applicator intended for use with Nucletron remote afterloading equipment for non-invasive brachytherapy. The applicator provides a means of positioning the HDR source near the breast to deliver radiation dose to the underlying tissue in areas of intact skin.

6. Comparison of Technological Characteristics

All the devices use a surface application approach to provide radiation to tissue via a remote afterloader device; all are intended as accessories to remote afterloaders.

7 Performance Testing

The Advanced Radiation Therapy Breast Brachytherapy Applicator is a passive device. Performance testing was not required.

8 Statement of Equivalency

The ART Breast Brachytherapy Applicator is substantially equivalent to the predicates, which provide the same or similar functions. The intended use, statement of indications, and technological and performance characteristics of the ART Breast Brachytherapy Applicator supports the concept of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 6 2006

Mr. Raymond J. Bricault Jr.
Chief Operating Officer
Advanced Radiation Therapy, LLC
9 Linnell Circle
BILLERICA MA 01821-3902

Re: K060299
Trade/Device Name: ART Breast Brachytherapy Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: April 28, 2006
Received: May 1, 2006

Dear Mr. Bricault:

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.

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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

Indications for Use

510(k) Number (if known): K060299

Device Name: ART Breast Brachytherapy Applicator

Indications for Use:

The ART Breast Brachytherapy Applicator is a rigid applicator intended for use with Nucletron remote afterloading equipment for non-invasive brachytherapy. The applicator provides a means of positioning the HDR source on the periphery of the breast to deliver radiation dose to the underlying tissue in areas of intact skin.

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 Device Evaluation (ODE)

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060299
