K103215

Section 6 510(k) Summary

NOV 15 2010

1. 510(k) Summary (Revised 10-28-2010)

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Cianna Medical
TRADE NAME:	Cianna S1, SINGLE LUMEN BALLOON APPLICATOR
COMMON NAME:	Brachytherapy Applicator
CLASSIFICATION NAME:	Remote Controlled Radionuclide Applicator System, 21 CFR, 892.5700
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	JAQ

PREDICATE DEVICES: Mammosite Radiation Therapy System (K041929)

Substantially Equivalent To:
The Cianna S1 Single Lumen Balloon Applicator is substantially equivalent in intended use, principal of operation and technological characteristics to the Mammosite Radiation Therapy System (K041929).

Description of the Device Subject to Premarket Notification:

The Cianna S1 Single Lumen Balloon Applicator is a specialized applicator that is temporarily inserted into the target volume to facilitate the application of radiation to the target site in the treatment of carcinoma.

The Cianna S1 Single Lumen Balloon Applicator is provided sterile for single use and is disposable.

Indication for Use:

The Cianna S1, Single Lumen Balloon Applicator is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

Technical Characteristics:

The Cianna S1 Single Lumen Balloon Applicator has similar physical and technical characteristics to the predicate devices. The Cianna S1 Single Lumen Balloon Applicator

and the identified predicates all provide a catheter configuration to allow delivery of radioactive sources in a specific, known geometry, as prescribed by the clinician.

Performance Data:

Performance testing was conducted to evaluate and characterize the performance of the Cianna S1 Single Lumen Balloon Applicator. Preclinical testing conducted included valve and syringe stability, balloon inflation diameter assessment, afterloader compatibility, closed system verification and biocompatibility testing per ISO 10993-1. The Cianna S1 Single Lumen Balloon Applicator performed as intended and met all acceptance criteria.

Basis for Determination of Substantial Equivalence:

The Cianna S1 Single Lumen Balloon Applicator has the following similarities to the predicate device:

- Same intended use
- Same design
- Same operating principal
- Same mechanism of action
- Same technological characteristics

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Cianna S1 Single Lumen Balloon Applicator is determined by Cianna Medical, to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Cianna Medical
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

NOV 15 2010

Re: K103215
Trade/Device Name: Cianna S1, Single Lumen Balloon Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: October 29, 2010
Received: November 1, 2010

Dear Mr. Job:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

NOV 15 2010

510(k) Number (if known): _____

Device Name: Cianna S1, Single Lumen Balloon Applicator

Indications for Use:

The Cianna S1, Single Lumen Balloon Applicator is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

OR

Prescription Use __X__ (Per 21 CFR 801.109)

Over-The-Counter Use_____ (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103215