DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

February 25, 2016

iCAD, Inc.
% Mr. John DeLucia
VP, Regulatory Affairs, Quality Assurance, Clinical Affairs
98 Spitbrook Road, Suite 100
NASHUA NH 03062

Re: K153570
Trade/Device Name: Axxent Electronic Brachytherapy System Model 110 XP 1200
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: February 10, 2016
Received: February 11, 2016

Dear Mr. DeLucia:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153570

Device Name
Axxent® Electronic Brachytherapy System

Indications for Use *(Describe)*
The Axxent® Electronic Brachytherapy System Model 110 XP 1200 is a high dose rate Brachytherapy device for use with Axxent Applicators to treat lesions, tumors and conditions in or on the body where radiation is indicated. Only Xoft Axxent Surface Applicators can be used with the Axxent Electronic Brachytherapy System Model 110 XP 1200.

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.

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K153570

510(K) Summary

510(k) OWNER:

iCAD Inc.
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F: 603- 880-3843
Registered Establishment Number: 1225671

MANUFACTURER FACILITY:

Xoft Inc. a Subsidiary of iCAD Inc.
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San Jose, CA 95134
Registered Establishment Number: 3005594788

NAME OF CONTACT:

John A. DeLucia
VP, Regulatory Affairs, Clinical Affairs and Quality Assurance

DATE SUMMARY PREPARED AND REVISED: December 11, 2015/February 23, 2016

TRADE NAME: Axxent Electronic Brachytherapy System Model 110 XP 1200

COMMON NAME: Radiation Therapy System

CLASSIFICATION: Class II

CLASSIFICATION NAME: X-ray Radiation Therapy System

CRF CLASSIFICATION: 21 CFR 892.5900

PRODUCT CODE: JAD

510(K) Summary (con't)

Legally Marketed Devices to Which Substantial Equivalence is Claimed

The Axxent Electronic Brachytherapy System is substantially equivalent to the following legally marketed predicate device.

Device Name	Manufacturer	510(k) Reference #	Concurrence Date
Axxent Electronic Brachytherapy System	Xoft	K122951	01/17/2013

Device Description

The Axxent Electronic Brachytherapy System consists of two primary components: the Axxent System Controller (Controller); the Axxent HDR X-ray Source-2.2 (Catheter/Source). The System is designed to deliver doses of X-ray radiation to tissue in proximity to the applicator using a miniature X-ray tube powered by the Controller.

The Axxent Electronic Brachytherapy System is a mobile, computer-controlled platform that is responsible for the overall operation of the System. The Controller is designed to work with the Source, which is a miniature X-ray tube located at the end of a flexible catheter. The Catheter/Source is inserted into a lumen of an appropriate Applicator which are cleared separately under their 510(k). The Axxent Electronic Brachytherapy System Model 110 XP 1200 described in this 510(k) will only be used for surface applications using Xoft Axxent Surface Applicators.

Intended Use / "Indications for Use"

The Axxent® Electronic Brachytherapy System Model 110 XP 1200 is a high dose rate Brachytherapy device for use with Axxent Applicators to treat lesions, tumors and conditions in or on the body where radiation is indicated. Only Xoft Axxent Surface Applicators can be used with the Axxent Electronic Brachytherapy System Model 110 XP 1200.

Summary of Technological Characteristics

The technological characteristics of the Axxent Electronic Brachytherapy System Controller are the same as the Axxent Electronic Brachytherapy Controller cleared in K122951. The table below describes the changes to the proposed Axxent Electronic Brachytherapy Controller.

Characteristic	Proposed Device	Predicate Device	Difference	Comments
Name	Axxent Electronic Brachytherapy System	Axxent Electronic Brachytherapy System	No Change	NA
Catalog Number	XP 1200	XP 1100	NA	NA
Part number	750-850	750-050	NA	NA
Indications for Use	Same	Same	No Change	NA
Software	Same	Same	No Change	NA
Hardware	Same	Same	No Change	NA
Pump Speed	120 rev/min	60 rev/min	Same pump with resistors removed	Two Resistors removed
Cooling Fluid	Galden HT-135	Water	Improve Cooling	Both cooling fluids
Cooling Cather Outer Material	Polyurethane 75D	HDPE	Longer Life	No Patient Contact
Anode Target	Tungsten Film	Tungsten Film	No Change	NA
Anode Target Thickness	1.5 microns	0.7 microns	Increased Thickness	Improve efficiency and life
Connectors on Cooling System	Kent Quick Connector	Luer	Improved Connector	Prevent new coolant use with older Axxent Electronic Brachytherapy System
Catheter/Source Interlock	No magnet	Magnet	Interlock not satisfied	Prevents use in non-surface indications

General Safety and Effectiveness Concerns
The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device. Risk management is ensured via a risk analysis which is used to identify potential hazards. Any potential hazards are controlled via software development, verification and validation testing.

Assessment of Non-Clinical Performance Data
Validation testing was performed and all performance, functional and system requirements were met. A number of non-clinical tests were conducted to support substantial equivalence. These included testing that demonstrated:

- Equivalence with the current device for spatial parameters (azimuthal and polar variation) and depth dose
- Equivalence between the current x-ray source/catheter used in the surface applicator and the proposed source/catheter through measurement of the depth dose
- Equivalence through the agreement of the first and second half value layers measured for the current x-ray source/catheter and the proposed source/catheter
- Consistency between spatial measurements, depth dose, and source/catheter spectrum after extended use of the proposed source/catheter
- The source/catheter output is linear as a function of time and reproducible.
- The proposed source/catheter functions for at least as long as the current source
- The proposed source/catheter are able to be used the same manner as the current x-ray source/catheter in a simulated clinical setting

This data has shown that the clinical dose is identical when using either source/catheter design in the surface applicator indication.

Conclusion
This traditional 510(k) for the Axxent® Electronic Brachytherapy System contains adequate information and data to determine substantial equivalence to the predicate devices.

The Axxent Electronic Brachytherapy System has the same intended use as the previously cleared predicate devices. Both are intended to be used to treat lesions, tumors and conditions in the body where radiation is indicated. The indications for use for the Axxent Electronic Brachytherapy System remain the same as its last clearance in K122951.

The Axxent Electronic Brachytherapy System has the same fundamental functional, scientific and performance characteristics as the previously cleared predicate device in that both devices are capable of providing radiation delivery through multiple channel applicators. The non-clinical data presented has shown that the clinical dose is identical when using the proposed or

current source/catheter design in the surface applicator indication. There are no new concerns of safety or efficacy with the proposed changes.