Xstrahl Ltd.
℅ Vineet Gupta
Technical Director
Unit 2 Maybrook Industrial Estate Maybrook Road
Brownhills, West Midlands WS8 7DG
UNITED KINGDOM

July 13, 2023

Re: K230611
Trade/Device Name: X80 / RADiant / PhotoElectric Therapy System (RADiant Aura)
Regulation Number: 21 CFR 892.5900
Regulation Name: X-Ray radiation therapy system
Regulatory Class: Class II
Product Code: JAD
Dated: March 3, 2023
Received: March 6, 2023

Dear Vineet Gupta:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lora D. Weidner -S

Digitally signed by Lora D. Weidner -S
Date: 2023.07.13 11:10:11 -04'00'

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230611

Device Name
X80 / RADiant / Photoelectric Therapy System (RADiant Aura)

Indications for Use *(Describe)*

The Xstrahl Photoelectric Therapy System is a low energy X-Ray system intended for superficial radiotherapy and surface electronic brachytherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.

Typical applications include treatment for Basal Cell Carcinoma, Squamous Cell Carcinoma, Metatypic Carcinoma, Cutaneous Appendage Carcinoma, Karposi's Sarcoma, Merkel Cell Carcinoma, Lentigo Maligna, Lentigo Maligna Melanoma, Cutaneous Lymphomas (B and T cell) and Keloids.

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)

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510(K) SUMMARY K230611

A. SUBMITTERS NAME

Xstrahl Ltd.

FDA Establishment Registration No. 3004561814

B. ADDRESS

Unit 2, Maybrook Industrial Estate
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Brownhills, West Midlands
WS8 7DG United Kingdom

C. CONTACT

Name:	Vineet Gupta, Ph.D.
Designation:	Technical Director
Phone:	(412) 320 5048
Email:	vineetgupta@xstrahl.com

D. DATE PREPARED:

3-March-2023

E. DEVICE NAME:

Device Trade Name:	X80 / RADiant / PhotoElectric Therapy System
Classification Name:	X-Ray Radiation Therapy System
Model / Market Name:	RADiant Aura

F. DEVICE CLASS:

Device Class:	II
Panel:	Radiology
Product Code:	JAD
Regulation Number:	21CFR 892.5900

G. PREDICATE DEVICES:

X80 / RADiant / PhotoElectric Therapy System (K172080)

H. STATEMENT ON INDICATIONS FOR USE:

The intended use and indications for use of the system have not changed due to the modification to the product. The modification has not changed the fundamental operating principle of the product.

Intended Use

The Xstrahl Photoelectric Therapy System is a low energy X-Ray system intended for superficial radiotherapy and surface electronic brachytherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.

Indications for Use

The Xstrahl Photoelectric Therapy System is a low energy X-Ray system intended for superficial radiotherapy and surface electronic brachytherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.

Typical applications include treatment for Basal Cell Carcinoma, Squamous Cell Carcinoma, Metatypic Carcinoma, Cutaneous Appendage Carcinoma, Karposi's Sarcoma, Merkel Cell Carcinoma, Lentigo Maligna, Lentigo Maligna Melanoma, Cutaneous Lymphomas (B and T cell) and Keloids.

I. DEVICE DESCRIPTION:

The X80 / RADiant / Photoelectric Therapy System (hereafter referred to as the RADiant System) is a compact and ergonomic superficial X-Ray therapy system operating in the 10kV to 80kV range intended for superficial radiotherapy and surface electronic brachytherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.

The RADiant System is a standalone X-Ray radiation therapy system consisting of the X-Ray Therapy Unit, a TP2 Central Control Unit (CCU), a Control POD (Control POD), and a PC on which user interface software is loaded. The system has a time-based control system used with treatment filters and applicators. A range of bespoke treatment applicators and beam filters are available for use with the RADiant System.

The system is freestanding, self-contained, unobtrusive, compact and ergonomic in design, which helps to ensure a reassuring and stress-free patient experience. The system is floor mounted in order to accommodate almost any clinical space, and features ergonomically designed controls ensuring smooth adjustment and safe, simple patient set-up. The system requires connection to the clinical facilities electrical supply and room interlocks.

The system is intended for use within a hospital or other clinical environment where the patient is treated under ‘outpatient’ conditions by trained medical professionals only e.g. Radiographers, Clinicians and Oncologists. It is not intended for use by a patient or general public. The clinical environment typically consists of a safety-interlocked lead lined shielded Treatment Room housing the X-Ray Therapy Unit, the TP2 Central Control Unit and an Emergency Stop Button, with a Control Room housing the Control POD

and the PC. Door interlocks and warning lights are located at the access point to the treatment room. The operator is located outside the treatment room during the treatment process.

J. PREDICATE DEVICE INFORMATION:

The RADiant Aura system is substantially equivalent to its primary predicate device RADiant (K172080; Decision Date: 29-September-2017).

The fundamental scientific technology of the RADiant Aura System with respect to its predicate device (RADiant system) has not changed. The intended use and indications for use of the device have not changed. Based upon the performance testing results for RADiant Aura (as detailed in the submission), the system raises no new issues of safety or effectiveness.

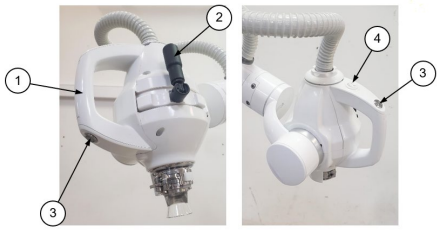
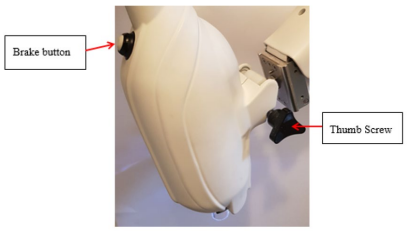
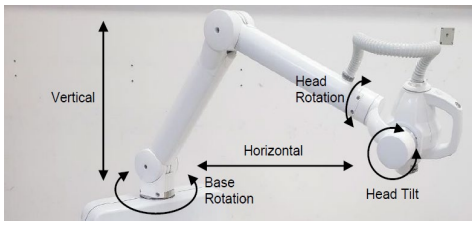
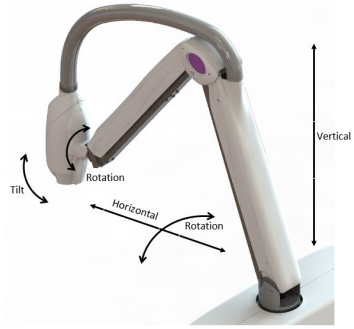
K. COMPARISON TO THE PREDICATE DEVICE:

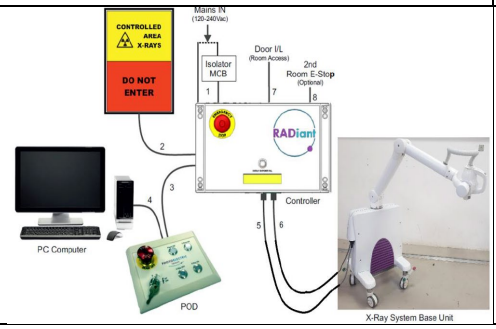
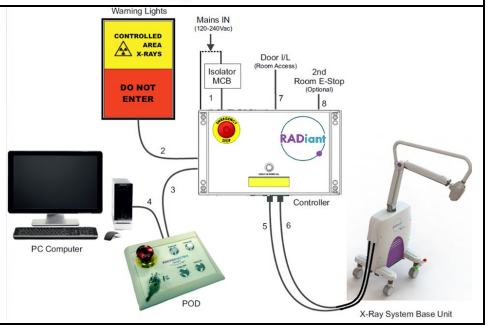
This section provides the summary of comparison of the RADiant Aura system to its predicate device.

Table 1: Comparison of the Subject Device with Predicate Device

Sr. No.	Comparison Item	Subject Device RADiant Aura (X80 / RADiant / Photoelectric Therapy System) (K230611)	Predicate Device X80 / RADiant / Photoelectric Therapy System (K172080)
1.	Intended Use	The Xstrahl Photoelectric Therapy System is a low energy X-Ray system intended for superficial radiotherapy and surface electronic brachytherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.	The Xstrahl Photoelectric Therapy System is a low energy X-Ray system intended for superficial radiotherapy and surface electronic brachytherapy treatment of primary malignant epithelial neoplasms of the skin and keloids.
2.	Indications for Use	The Xstrahl Photoelectric Therapy System is a low energy X-Ray system intended for superficial radiotherapy and surface electronic brachytherapy treatment of primary malignant epithelial neoplasms of the skin and keloids. Typical applications include treatment for Basal Cell Carcinoma, Squamous Cell Carcinoma, Metatypic Carcinoma, Cutaneous Appendage Carcinoma, Karposi's Sarcoma, Merkel Cell Carcinoma, Lentigo Maligna, Lentigo Maligna Melanoma, Cutaneous Lymphomas (B and T cell) and Keloids.	The Xstrahl Photoelectric Therapy System is a low energy X-Ray system intended for superficial radiotherapy and surface electronic brachytherapy treatment of primary malignant epithelial neoplasms of the skin and keloids. Typical applications include treatment for Basal Cell Carcinoma, Squamous Cell Carcinoma, Metatypic Carcinoma, Cutaneous Appendage Carcinoma, Karposi's Sarcoma, Merkel Cell Carcinoma, Lentigo Maligna, Lentigo Maligna Melanoma, Cutaneous Lymphomas (B and T cell) and Keloids.
3.	FDA Product Code	JAD	JAD

Sr. No.	Comparison Item	Subject Device RADiant Aura (X80 / RADiant / Photoelectric Therapy System) (K230611)	Predicate Device X80 / RADiant / Photoelectric Therapy System (K172080)
4.	FDA Class	II	II
5.	FDA Classification Name	X-Ray Radiation Therapy System	X-Ray Radiation Therapy System
6.	FDA Regulation Number	21CFR 892.5900	21CFR 892.5900
7.	Physical Characteristics		
7a.	Basic Design	Base unit, with 4 lockable wheels, contains the x-ray generator and cooler. X-Ray tube head is mounted on a support arm that is mounted on the base unit.	Base unit, with 4 lockable wheels, contains the x-ray generator and cooler. X-Ray tube head is mounted on a support arm that is mounted on the base unit.
7b.	Base Unit Dimension	52 cm (D) x 57 cm (W) x 55 cm (H)	52 cm (D) x 57 cm (W) x 55 cm (H)
7c.	CCU Dimension	28 cm (W) x 140 cm (H) x 170 cm (D)	28 cm (W) x 140 cm (H) x 170 cm (D)
7d.	POD Dimension	20 cm (W) x 7.5 cm (H) x 150 cm (D)	20 cm (W) x 7.5 cm (H) x 150 cm (D)
8.	ARM Specifications		
8a.	Maximum Weight Supported	8 kg	4.5 kg
8b.	Rotation about the base unit	± 95° (Total rotation is the same with reference to 0 degrees)	± 180° (Total rotation is the same with reference to 0 degrees)
8c.	Vertical Range	125.7 cm to -23 cm	59.5 cm to -23 cm
8d.	Horizontal Range	8.5 cm to 118 cm	43 cm to 105 cm
8e.	Number of electromagnetic brakes	2 (1 between vertical arm and base unit and 1 between vertical and horizontal arm)	2 (1 between vertical arm and base unit and 1 between vertical and horizontal arm)
8f.	Number of gas struts	4 (all 4 of them in the vertical arm: two of them to control the vertical arm motion and two of them to control the horizontal arm motion)	2 (one in vertical arm and 1 in horizontal arm)
9.	X-Ray Tube Head Specifications		
9a.	X-Ray Tube Manufacturer	Varex Imaging	Varex Imaging
9b.	Source Voltage	10 kV to 80 kV	10 kV to 80 kV
9c.	Model Number	VF-80	VF-80
9d.	Continuous Max Tube Power	100 W	100 W
9d.	Rotation of the Tube Head	± 110°	± 90°
9e.	Tilt of the Tube Head	± 45°	+ 90° to - 15°
9f.	Vertical Motion	0 -1 cm	None
9e.	Number of Electromechanical Brakes	2 (one to control the head rotation and the other to control the head tilt)	None. This is based on a single mechanical locking mechanism

Sr. No.		Comparison Item	Subject Device RADiant Aura (X80 / RADiant / Photoelectric Therapy System) (K230611)	Predicate Device X80 / RADiant / Photoelectric Therapy System (K172080)
	9f.	Image of Tube Head and controls	 1. Tube head movement handle 2. Tube head vertical movement handle 3. Movement enable button for arm and head joints movement. Either button can be used. 4. LED light ring switch	 • Brake Button is the movement enable button for the arm joints movement • Thumb screw is the mechanical locking mechanism for head movement
10.		Image showing arm and head movement labels		
11.		Base Unit Components		
	11a.	X-Ray Generator	Spellman Power: 100 W KV Range: 0 to 80 kV mA Range: 0 to 2 mA	Spellman Power: 100W KV Range: 0 to 80 kV mA Range: 0 to 2 mA
	11b.	Cooling System	Type: Air-cooled water-cooling system Pump: Laing D5-Pump 12V D5-Vario Fan: 2 off 120 mm Noctua	Type: Air-cooled water-cooling system Pump: Laing D5-Pump 12V D5-Vario Fan: 180mm Silverstone
	11c.	Number of PCBs in the Base Unit	2	5
12.		Applicators		
	12a.	Max Focal Spot Distance (FSD) supported	10 cm	10 cm
	12b.	Standard Applicator kit	Electronic Brachytherapy: 5 cm FSD (1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm) Superficial Radiation Therapy: 6 cm FSD (1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm)	Electronic Brachytherapy: 5 cm FSD (1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm) Superficial Radiation Therapy: 6 cm FSD (1 cm, 1.5 cm, 2 cm, 3 cm, 4 cm)

Sr. No.		Comparison Item	Subject Device RADiant Aura (X80 / RADiant / Photoelectric Therapy System) (K230611)	Predicate Device X80 / RADiant / Photoelectric Therapy System (K172080)
	12c.	Applicator Material	Clear Cast Acrylic (PMMA)	Clear Cast Acrylic (PMMA)
13.		Filters		
	13a.	Filter Material	Aluminum	Aluminum
	13b.	Standard Filter thickness	2.5 mm Al and 1.5 mm Al	2.5 mm Al and 1.5 mm Al
14.		Software		
	14a.	Concerto	Version: 2.3	Version 2.3
	14b.	Fisica	Version: 1.06	Version: 1.06
	14c.	TP2	Version: 1.24	Version: 1.24
15.	System Image			
16.	Overall System Architecture			

RADiant Aura contains all the features and components for the operation of the system as present in the predicate device. RADiant Aura enhances the design of the arm and the head joint of the system. The similarities and differences are described in detail as part of this submission.

RADiant Aura's (subject device (K230611) fundamental technological characteristics are the same as those of the predicate device (K172080). The x-ray tube (VF-80) and the generator (Spellman) used on both the systems are the same. The control system on the subject device (K230611) and the predicate device (K172080) is also the same. The firmware and the software used on both the devices (predicate (K172080) and subject (K230611)) are also the same. The overall system architecture of both the systems is also the same.

In addition, the target population and the indications for use are similar to that of the predicate device. Any minor differences in the features do not raise any concerns for safety, performance, or effectiveness of the

device. The characteristics / features of RADiant Aura with respect to the predicate device is described in the comparison chart in the submission.

L. SUMMARY OF TESTING:

Design verification and validation testing was performed to ensure that the device functionality works as per its intended use, all risks are mitigated, is substantially equivalent, and the product conforms to the required standards.

Non-clinical testing, including verification of risk control measures, was completed and detailed results of these tests are included as part of this submission. Twenty Six independent verification tests and 18 independent validation tests were executed on the RADiant Aura systems. These tests included testing the system for its retention of the applicator and filter during various ranges of motion, residual motion of the system, system's response to power loss, system stability testing, radiation leakage testing, build of the individual components and the complete system. Software run-through functionality test was also completed successfully. The versions of the software used in predicate device (K17208) worked without any changes with the RADiant Aura system. Testing was also completed to ensure that the system's ability to position the treatment head to treat different locations while the patient was laying on the bed or was in seated position was not affected by the design changes with respect to the predicate device.

Testing was also completed successfully that determined the dose reproducibility in accordance with BS EN 60601-2-8:2015+A1:2016 clause 201.10.1.2.112 'Agreement between indicated values and effective values.'

In addition, independent output measurements were completed successfully at the National Physics Laboratory UK (NPL) as per Xstrahl Customer Acceptance Test procedure and to verify compliance with the following recognized codes of practice:

- AAPM. (2001). AAPM protocol for 40-300kV x-ray beam dosimetry in radiotherapy and radiobiology.
- IPEMB. (1996). The IPEMB code of practice for the determination of absorbed dose for x-rays below 300kV generating potential (0.035 mm Al-4 mm Cu HVL; 10-300kV generating potential).

Conclusion:

The verification and validation results demonstrate that the RADiant Aura system met its design requirements and specifications, is substantially equivalent to its predicate device, and conforms to the applicable sections of standards that includes:

- IEC 60601-1: Medical Electrical Equipment – General Requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-2-8: Medical electrical equipment - Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366: Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304: Medical device software - Software life cycle processes
- ISO 14971: Medical devices - Application of risk management to medical devices