Dear Mr. Mullen:

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 (DICE) 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 (DICE) 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,

Michael O. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Summary
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. **Submitter’s name and address:**
Xstrahl Limited
Unit 2 Maybrook Industrial Estate
Maybrook Road
Walsall Wood
Brownhills
West Midlands
WS8 7DG
U.K.

FDA Establishment Registration No. 3004561814

2. **Submitter’s telephone number and fax number:**
Tel: 011 44 1543 688920
Fax: 011 44 1543 688928

3. **Contact person:**
Mr. Andrew Mullen, Operations Director

4. **Date this 510(k) summary prepared:**
June 30th 2017

5. **Trade/proprietary name of the device:**
Photoelectric Therapy System

6. **Classification name and number of the device:**
FDA Class – II
FDA Product Code: JAD
FDA Classification Name: X-Ray Radiation Therapy System
FDA Regulation Number: 21CFR 892.5900

7. **Legally marketed predicate device to which substantial equivalence is claimed:**

<table>
<thead>
<tr>
<th><strong>Device Manufacturer</strong></th>
<th>Sensus Healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device Name</strong></td>
<td>SRT-100 Superficial Radiation Therapy System</td>
</tr>
<tr>
<td><strong>FDA 510(k) No.</strong></td>
<td>K123985</td>
</tr>
<tr>
<td><strong>Clearance given by FDA to market this device on</strong></td>
<td>May 14th 2013</td>
</tr>
<tr>
<td><strong>FDA Class</strong></td>
<td>II</td>
</tr>
<tr>
<td><strong>FDA Product Code</strong></td>
<td>JAD</td>
</tr>
</tbody>
</table>
8. Description of the device that is the subject of this premarket notification:

The Photoelectric Therapy 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 Photoelectric Therapy 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 Photoelectric Therapy 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.

9. Intended use and indication 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, Kaposi's Sarcoma, Merkel Cell Carcinoma, Lentigo Maligna, Lentigo Maligna Melanoma, Cutaneous Lymphomas (B and T cell) and Keloids.
The system, which is intended to be used by trained medical professionals, is compact and ergonomic and with its ease of use and installation can be utilised in hospital oncology centres, in addition to smaller dermatology and oncology practices.

10. Technological characteristics:

The primary application for the Photoelectric Therapy System is non-surgical non-melanoma skin cancer treatment. With the system being sufficiently small, ergonomic, with ease of use and installation such that it could be utilised in hospital oncology centres, in addition to smaller dermatology and oncology practices.

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 feature ergonomically designed controls ensuring smooth adjustment and patient set-up with a flexibility that allows patients to be treated in any position. The system requires connection to the clinical facilities electrical supply and safety circuits.

The system comprises a small freestanding base unit, with a footprint measuring 550mm x 550mm, incorporating 4 total-locking wheel castors, permitting movement of the base unit and X-Ray treatment head within the treatment room, with the system fixed in place prior to treatment with operation of a single foot lever.

The Control POD and PC are located in the control room, with the PC connecting to the Control POD by a USB cable. A single cable connects the POD and the TP2 Central Control Unit between the control room and the controller.

The TP2 Central Control Unit is wall mounted in the treatment room, with two small cables connecting to the X-Ray Therapy Unit.

An Emergency Stop button is incorporated on the controller, and provision for a second Emergency Stop to be fitted within the treatment room.
Summary of the Technological Characteristics of the Device compared with the Predicate Device

<table>
<thead>
<tr>
<th>Feature</th>
<th>Candidate Device: Xstrahl Ltd. Photoelectric Therapy System</th>
<th>Predicate Device: Sensus Healthcare SRT-100 Superficial Radiation Therapy System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic design</td>
<td>Mobile base unit, with 4 lockable wheels, contains the X-Ray generator, the X-Ray tube head mounted on a support arm and the X-Ray tube cooling</td>
<td>Mobile base unit, with 4 lockable wheels, contains the X-Ray generator, power supply components, the X-Ray tube head mounted on a support arm, the X-Ray tube cooling system, and controls and indicators</td>
</tr>
<tr>
<td>Dimensions and Weight</td>
<td>Base Unit: The height of the base unit is 31” (80cm) and with the arm fitted the height is 54” (138cm). Weight 140lb (64kg). Footprint 22” (550mm) x 22” (500mm).</td>
<td>Base Unit: 67” H x 30 “ W x 30” D Weight 350lb (160kg) Footprint 30” (762mm) x 30” (762mm). Control Console: 9.5” H x 13.125” W x 7.25” D Weight 25lb (12kg)</td>
</tr>
<tr>
<td></td>
<td>TP2 Central Control Unit: 11” (275mm) W x 5.5” (140mm) H x 6.5” (165mm) D Weight 11lb (5kg)</td>
<td></td>
</tr>
<tr>
<td>Voltage</td>
<td>100 - 240 VAC</td>
<td>100-120V 220-240V</td>
</tr>
<tr>
<td>Mains Frequency</td>
<td>50-60Hz</td>
<td>50-60Hz</td>
</tr>
<tr>
<td>X-Ray Source Voltage</td>
<td>10 kV to 80 kV</td>
<td>50kV at 10mA 1.0mm Al HVL 70kV at 10mA 1.0mm Al HVL 100 kV at 8mA 2.0mm Al HVL</td>
</tr>
<tr>
<td>Operating Temperature Range</td>
<td>15ºC to 30ºC (59ºF to 86ºF)</td>
<td>10ºC to 30ºC (50ºF to 86ºF)</td>
</tr>
<tr>
<td>Operating Relative Humidity Range</td>
<td>10 to 80% (non-condensing)</td>
<td>30% to 70% (non-condensing)</td>
</tr>
<tr>
<td>Operating Temperature Range</td>
<td>15ºC to 30ºC (59ºF to 86ºF)</td>
<td>10ºC to 30ºC (50ºF to 86ºF)</td>
</tr>
</tbody>
</table>
### Feature | Candidate Device: Xstrahl Ltd. Photoelectric Therapy System | Predicate Device: Sensus Healthcare SRT-100 Superficial Radiation Therapy System
--- | --- | ---
Treatment Applicators | Standard Circular Applicators are available in the following diameters: available in the following diameters: 1.5cm, 2.0cm, 3.0cm, 4.0cm and 5.0cm, all 5 cm FSD. Optional Oval Lip Applicators are available in the following diameters: 1.0cm x 1.5cm, 1.0cm x 2.0cm, 1.0cm x 3.0cm, 1.5cm x 3.0cm and 1.5 cm x 4.0cm diameter, all at 5 cm FSD. | Standard Circular Applicators are available in the following diameters: 1.5cm, 1.5cm, 2.0cm, 2.5cm, 3.0cm, 4.0cm and 5.0cm, all at 15 cm SSD 10.0cm and 12.7cm, both at 25 cm SSD Optional Circular Applicator; 1.0cm at 15 cm SSD is available.
Filters | Standard Filters are available with the following values; 1.85mm Al HVL and 2.5mm Al HVL. | Standard Filters are available with the following values; 1.3mm Al HVL and 2.1mm Al HVL.

### 11. Summary of Non-clinical Tests Undertaken

IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance. Collateral standard. Usability

EN 60601-2-8 (IEC-60601-2-8) Medical Electrical Equipment Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV

EN 60601-1-2 (IEC 60601-1-2) Medical Electrical Equipment Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – requirements and tests

IEC 62366 Medical Devices – Application of usability engineering to medical devices
Additionally independent measurements were completed at the National Physics Laboratory UK (NPL) to verify compliance with the following recognized codes of practice and Xstrahl Customer Acceptance Test (CAT) procedure

IPEMB Code of Practice Phys. Med. Biol. 41 (1996) 2605–2625. Institute of Physics and Engineering in Medicine and Biology (IPEMB), Code of Practice for the determination of absorbed dose for x-rays below 300 kV generating potential (0.035 mm Al–4 mm Cu HVL; 10–300 kV generating potential)

American Association of Physicists in Medicine (AAPM) Task Group 61 (TG-61), Protocol for 40–300 kV x-ray beam dosimetry in radiotherapy and radiobiology

This concludes the 510(k) Summary.