Xstrahl Ltd.
Gupta Vineet
Chief Technology Officer
Unit 2 Maybrook Industrial Estate Maybrook Road
Brownhills, West Midlands WS8 7DG
United Kingdom

December 4, 2024

Re: K240671
Trade/Device Name: XBeam (v2)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ
Dated: March 10, 2024
Received: March 11, 2024

Dear Gupta Vineet:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240671

Device Name
XBeam (v2)

Indications for Use *(Describe)*
The XBeam Software can be used for validating the monitor units or radiation dose to a point that has been calculated by hand or another treatment planning system for external beam radiation therapy. In addition, the XBeam Software can also be used as a primary means of calculating the monitor units or radiation dose to a point for external beam radiation treatments.

XBeam is only intended to be used with Xstrahl's superficial and orthovoltage radiotherapy and surface electronic brachytherapy systems. XBeam is intended to be used by authorized personnel trained in medical physics.

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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K240671

510(K) SUMMARY

A. SUBMITTERS NAME

Xstrahl Ltd.

FDA Establishment Registration No. 3004561814

B. ADDRESS

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

C. CONTACT

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

D. DATE PREPARED:

03-December-2024

E. DEVICE NAME:

Device Trade Name: XBeam
Classification Name: Medical Charged-Particle Radiation Therapy System
Common Name: System, Planning, Radiation Therapy Treatment

F. DEVICE CLASS:

Device Class: Panel: II
Product Code: Radiology
Regulation Number: MUJ
21CFR 892.5050

G. PREDICATE DEVICES:

RADCalc (K193381)

H. STATEMENT ON INDICATIONS FOR USE:

The XBeam Software can be used for validating the monitor units or radiation dose to a point that has been calculated by hand or another treatment planning system for external beam radiation therapy. In addition, the XBeam Software can also be used as a primary means of calculating the monitor units or radiation dose to a point for external beam radiation treatments.

XBeam is only intended to be used with Xstrahl's superficial and orthovoltage radiotherapy and surface electronic brachytherapy systems. XBeam is intended to be used by authorized personnel trained in medical physics.

I. DEVICE DESCRIPTION:

XBeam is a standalone dose calculation software for Xstrahl's medical devices. These devices include:

- Xstrahl 100, Xstrahl 150, Xstrahl 200, Xstrahl 300 (K962613)
- X80 RADiant Photoelectric Therapy System (K172080)
- RADiant Aura (X80 RADiant Photoelectric Therapy System) (K230611)

XBeam's dose calculation algorithm can be used to determine the beam-on time or monitor units based on the applicator and filter selected for the specific device. The beam-on time / monitor units are calculated based on the percent dose depth (PDD) curve and the absolute dose output for the specified applicator-filter combination. The software allows for calculating treatment parameters for single or two (parallel opposed) beams.

XBeam is intended to be used within a clinical environment where the patient is treated with Xstrahl's medical systems. XBeam is intended to be used by authorized personnel trained in medical physics. It is not intended to be used by patients or general public.

J. PREDICATE DEVICE INFORMATION:

The XBeam software is substantially equivalent to its primary predicate device RADCalc (K193381; Decision Date: 31-Dec-2019).

The fundamental scientific technology of XBeam with respect to its predicate device (RADCalc) for dose calculation for Xstrahl's medical devices is the same. The intended use and indications for use of the XBeam software is similar to that of the RADCalc software.

K. COMPARISON TO THE PREDICATE DEVICE:

This section provides the summary of comparison of XBeam to its predicate device.

Table 1 Indications for Use Comparison

	Proposed Device XBeam v2 (K240671)	**Predicate Device RADCalc (K193381)**
Device Trade Name	XBeam	RADCalc
Intended Use / Indications for Use	The XBeam Software can be used for validating the monitor units or radiation dose to a point that has been calculated by hand or another treatment planning system for external beam radiation therapy. In addition, the XBeam Software can also be used as a primary means of calculating the monitor units or radiation dose to a point for external beam radiation treatments. XBeam is only intended to be used with Xstrahl's superficial and orthovoltage radiotherapy and surface electronic brachytherapy systems. XBeam is intended to be used by authorized personnel trained in medical physics.	1. RadCalc performs a secondary dose calculation verification on the treatment plan done by the treatment planning software. This is RadCalc's primary function. Radiation therapy systems typically calculate the monitor units needed to deliver the desired amount of radiation to a point of reference within the patient. In this situation, RadCalc will serve to validate those monitor units computed by the primary radiation therapy planning system. Additional verification activities revolve around point dose comparisons, 3D dose evaluation via Gamma analysis, and DVH comparisons. It is not the intention of RadCalc to replace the calculation performed by the primary radiation therapy planning computer but to validate its calculation as a means of quality assurance. The practice of performing a secondary check is recommended by the American Association of Physicists in Medicine (AAPM) Task Group 40 as part of a good quality assurance program. This practice is an important aspect in providing quality patient care. 2. Import data from the treatment planning software and export the data from the treatment planning system to the verify and record system, which is the device that actually controls the radiation beam. This will reduce the number

		of errors that occur as a result of manually inputting this data. 3. In addition to performing the secondary dose verification calculation, RadCalc can also be used as the primary means of calculating monitor units in situations where the physician does not order the use of a radiation therapy treatment plan. RadCalc can independently calculate the amount of radiation the beam should produce (called the MU or monitor unit) to deliver to the patient the radiation dose the doctor recommends. This function is usually only used in urgent, emergency situations. 4. In addition, RadCalc performs brachytherapy-type calculations. Fo brachytherapy calculations, High Dose Rate (HDR), Low Dose Rate (LDR), and Permanent type treatments can be verified. Verification activities revolve around point dose comparisons, 3D dose evaluation via Gamma analysis, and DVH comparisons. RadCalc is not used as a primary means of calculating patient dose for brachytherapy treatments. 5. Analysis affluence and dose maps can be performed via percentage difference, distance to agreement, or gamma analysis methodologies. 6.Interoperability with external dose calculation engines (EDCE) by sending them treatment plans and associated information in their necessary format so that the EDCE can perform a 3D dose calculation using its dose calculation algorithm. The computed dose volume is received back and the 3D analysis tools described above are used to compare against the treatment planning system.

Table 2 General Comparison

	Proposed Device XBeam v2 (K240671)	**Predicate Device RADCalc (K193381)**
Product Code	MUJ	MUJ
Class	II	II
Regulation Number	21CFR 892.5050	21CFR 892.5050
Classification Name	Medical Charged-Particle Radiation Therapy System	Medical Charged-Particle Radiation Therapy System
Common Name	System, Planning, Radiation Therapy Treatment	System, Planning, Radiation Therapy Treatment
Devices Supported	X80 (RADiant / RADiant Aura), Xstrahl 100, Xstrahl 150, Xstrahl 200, Xstrahl 300	X80 (RADiant / RADiant Aura), Xstrahl 100, Xstrahl 150, Xstrahl 200, Xstrahl 300
Treatment Types Supported		
Brachytherapy	No	Yes
Superficial / Orthovoltage (kV)	Yes	Yes
Tomotherapy	No	Yes
Photons (MV)	No	Yes
Electrons	No	Yes
Workflow Comparison		
Beam Data Input	Yes	Yes
Patient Information	Yes	Yes
Prescription	Yes	Yes
Treatment Time / Monitor Units Calculation	Yes	Yes
Print Reports	Yes	Yes
Beam Data Inputs / Setup		
Machine Type	Yes	Yes
Filter (mm)	Yes	Yes
HVL (mm)	Yes	Yes
Applicator Type	Yes	Yes
Focal Spot Distance (FSD)	Yes	Yes
kVp	Yes	Yes
mA	Yes	Yes
Prescription		
Prescribed Dose (cGy)	Yes	Yes
Dose Per Fraction (cGy)	Yes	Yes
Number of Fractions	Yes	Yes
Number of Beams	1 and 2	1 and 2
Stand Off (cm) (Optional)	Yes	Yes
Backscatter (Optional)	No	Yes
Cone / Custom Cutout (Optional)	Yes	Yes

For the treatment type supported, XBeam supports the required features and workflow steps that are present in the predicate device (K193381).

XBeam's fundamental technical characteristics are the same as those of the predicate device (K193381). In addition, the target population and the indications for use are similar to that of the predicate device (K193381). Any minor differences in the features do not raise any concerns for safety, performance, or effectiveness of the device. The characteristics / features of XBeam with respect to the predicate device is described in the comparison chart above.

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. The details of the design verification and validation activities were performed as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The verification activities included system tests, module tests, anomaly verification, code reviews, and run-though integration tests. Three hundred twenty-three (323) independent verification tests were executed. Tests that failed were re-executed. All the verification tests passed. The validation activities included clinical workflow, treatment planning, software usability, and dosimetric accuracy. The output of the dose calculation algorithm was validated by comparing it against two standard methods: hand calculations and RadCalc (version: 7.3). The results indicated that the output calculated by XBeam was the same as that calculated by hand calculation and by RADCalc. The maximum difference found was 0.7% which can be attributed to interpolation / rounding errors in calculation. The planned dose was also compared to the delivered dose to show that the treatment plan can be accurately delivered. The results indicate that the measured and planned dose values agree to within 3.6% for energies below 80kV. The overall measurement uncertainties were estimated at 5.5%, mainly due to the device used which has a 5% uncertainty on the measured dose. For energies above 80kV, the measured and planned dose values agree to within 1.8%, with measurement uncertainties estimated at 1.7%. This demonstrates that the errors in the measurements made fall largely within the expected uncertainties in the measurements. It also demonstrates that the XBeam-generated treatment times deliver the prescribed dose within the expected uncertainties, to accuracy levels acceptable within the radiotherapy community.

Based upon the performance testing results for XBeam, the system is substantially equivalent to its predicate device (RADCalc) and raises no new issues related to safety or effectiveness.

Conclusion:

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

- 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