April 6, 2026

RICOH 3D for Healthcare, LLC
Kim Torluemke
Director Regulatory Affairs & Quality
5575 Venture Drive Unit A
Parma, Ohio 44130

Re: K253025
Trade/Device Name: Ricoh 3D for Healthcare Bolus
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: Class II
Product Code: IXI
Dated: September 19, 2025
Received: September 19, 2025

Dear Kim Torluemke:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253025

Device Name
Ricoh 3D for Healthcare Bolus

Indications for Use *(Describe)*
The Ricoh 3D for Healthcare Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. Ricoh 3D for Healthcare Boluses are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. The Ricoh 3D for Healthcare Bolus product must be verified and approved by the radiation therapy professional prior to use on a patient. The Ricoh 3D for Healthcare Bolus is intended for patients of all ages receiving radiotherapy treatment.

Ricoh 3D for Healthcare Bolus was evaluated using 6 MV photons, 6 MeV electrons, and 9 MeV electrons and has not been assessed for use with protons or orthovoltage X-rays.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Ricoh 3D for Healthcare, LLC
5575 Venture Drive Unit A
Parma, Ohio | USA | 44130
Tel: +1.631.864.0311
Email: Bob.Lemendola@RicohUSA.com

Contact Person: Kim Torluemke
Date Prepared: March 30, 2026

II. DEVICE

Name of Device:	Ricoh 3D for Healthcare Bolus
Classification Name:	Radiation therapy beam-shaping block
Regulation:	21 CFR §892.5710
Regulatory Class:	Class II
Product Classification Code:	IXI

III. PREDICATE & REFERENCE DEVICES

Predicate Manufacturer:	VHA Office of Advanced Manufacturing - Ft. Lawton
Predicate Trade Name:	VHA Radiotherapy Bolus
Predicate 510(k):	K222639

IV. DEVICE DESCRIPTION

The Ricoh 3D for Healthcare Bolus is a patient-specific device placed on the patient's skin as a radiotherapy accessory intended to help control the radiation dose received by the patient. Ricoh 3D Healthcare Boluses are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of the beam from a radiation therapy source. It helps to match delivered dosage with the physician prescribed treatment plan.

V. INDICATIONS FOR USE

The Ricoh 3D for Healthcare Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. Ricoh 3D for Healthcare Boluses are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. The Ricoh 3D for Healthcare Bolus product must be verified and approved by the radiation therapy professional prior to use on a patient. The Ricoh 3D for Healthcare Bolus is intended for patients of all ages receiving radiotherapy treatment.

Ricoh 3D for Healthcare Bolus was evaluated using 6 MV photons, 6 MeV electrons, and 9 MeV electrons and has not been assessed for use with protons or orthovoltage X-rays.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

	Ricoh 3D for Healthcare Bolus	**VHA Radiotherapy Bolus**	**Comments on SE**
Indications for Use	The Ricoh 3D for Healthcare Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. Ricoh 3D for Healthcare Boluses are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. The Ricoh 3D for Healthcare Bolus product must be verified and approved by the radiation therapy professional prior to use on a patient. The Ricoh 3D for Healthcare Bolus is intended for patients of all ages receiving radiotherapy treatment. Ricoh 3D for Healthcare Bolus was evaluated using 6 MV photons, 6 MeV electrons, and 9 MeV electrons and has not been assessed for use with protons or orthovoltage X-rays.	The VHA Radiotherapy Bolus product is a device that will be placed on the skin of a patient as a radiotherapy accessory intended to help control the radiation dose received by the patient. VHA Radiotherapy Boluses are designed by radiation therapy professionals for a unique patient and are intended to modify the shape of a beam from a radiation therapy source. The VHA Radiotherapy Bolus product must be verified and approved by the radiation therapy professional prior to use on a patient. The VHA Radiotherapy Bolus is intended for patients of all ages receiving radiotherapy treatment. VHA Radiotherapy Bolus was evaluated using 6 MV photons and 9MeV electrons but has not been assessed for use with protons or at orthovoltage X-rays	The indications for use of the subject device are nearly identical to the predicate, differing only in the addition of 6MeV electrons.
Device Input	1. DICOM 2. The device is designed by the radiation therapy professional.	1. DICOM 2. The device is designed by the radiation therapy professional.	Same
Device Manufacturing Method	Additive Manufacturing (3D Printing)	Additive Manufacturing (3D Printing)	Same

	Ricoh 3D for Healthcare Bolus	VHA Radiotherapy Bolus	Comments on SE
Device Material	BIOMED Elastic 50A	VisiJet® M2E-BK70	Subject device uses stereolithography (SLA) technology with Shore 50A durometer material; predicate device uses multijet printing (MJP) technology with Shore 70A durometer material

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Verification Testing

The fit, geometric dimensions and degradation of printed Boluses was assessed via bench testing. Testing showed that the physical models met all specification and all acceptance criteria was met.

Validation Testing

Design requirements were assessed through design validation testing. The use of thermoluminescent dosimeters (TLDs) in phantom studies showed, that when the physical boluses were used, the dose distribution was satisfactory.

Biocompatibility Testing

Successful biocompatibility testing was performed in compliance with ISO 10993 for the indication and contact duration of the product.

Cleaning Validation Testing

The effectiveness of the cleaning method prescribed in the IFU was assessed through Cleaning and simulation validation.

Shipping Validation

Simulated distribution and handling testing was performed to assess the packaging for Ricoh 3D for Healthcare Bolus. Testing showed that the packaging adequately protects the product from damage throughout the distribution process.

VIII. CONCLUSIONS

A comparison of intended use and technological characteristics combined with performance data demonstrates that Ricoh 3D for Healthcare Bolus is substantially equivalent to the predicate device.