May 22, 2026

Anatomical Geometry S.L.
% Tyler Ting
Quality Director
Rook Quality Systems
1155 Mount Vernon Hwy
Suite 800
Dunwoody, Georgia 30338

Re: K252784
Trade/Device Name: eXaSkin Plus
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: MUJ, IXI
Dated: April 23, 2026
Received: April 23, 2026

Dear Tyler Ting:

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, 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)*
K252784

Device Name
eXaSkin Plus

Indications for Use *(Describe)*
eXaSkin is a medical device intended to be used as a bolus for the treatment of neoplastic skin lesions through radiotherapy. The product is designed to be applied to the irradiated area by qualified healthcare professionals to address anatomical irregularities and ensure precise delivery of the prescribed dose to the skin and underlying tissues during a radiation therapy treatment.

eXaSkin was evaluated using 6 MV photons but has not been assessed for use with 10 MV photons, protons, or orthovoltage X-rays.

eXaSkin Plus 150 and 225 is intended for general radiotherapy use.
eXaSkin Plus 650 is intended for use on breast tissue.

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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Submitter

Anatomical Geometry S.L.
Parque Industrial y de Servicios Aljarafe. C/ Formación Nº6,
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Date Prepared: 06 MAY 2025

Device

Trade Name:	eXaSkin Plus
Common Name:	Radiotherapy Bolus
Classification Name:	System, Planning, Radiation Therapy Treatment
Regulatory Class:	II
Product Code(s):	MUJ, IXI
Regulation Number:	892.5050, 892.5710
Classification Panel:	Radiology

Predicate Device

AnatGe submits the following information to demonstrate that the subject device eXaSkin Plus, is substantially equivalent to the following legally marketed predicate device:

510(k) Number	Device Name	Product Code
K211511	.decimal Bolus	MUJ, IXI

Reference Device

AnatGe submits the following information for the reference device utilized in the submission of the subject device:

510(k) Number	Device Name	Product Code
K812893	SUPERFLAB	IYP

Device Description

The eXaSkin Plus is a highly-adaptable bolus in a paste form that allows for a customizable bolus in 3 minutes. The eXaSkin Plus allows for precision dosage on the skin during photon beam therapy in clinical situations and is usable and specially recommended for highly-critical regions such as the scalp, hands,

neck, outer ear, facial contours, and genitals. The eXaSkin Plus eliminates build-up with less bolus thickness, does not dry, shrink, or break, and does not require complex 3D systems to achieve expected results.

The device enables the use of Surface Guided Radiotherapy (SGRT) technology. Unlike other SGRT-compatible boluses, eXaSkin is non-reflective and can be consistently repositioned at the same location on the patient's surface for each treatment session. As a result, it does not require an additional optical surface imaging (OSI) acquisition of the bolus itself. This allows for simultaneous patient positioning and bolus alignment in a single OSI step.

Indications for Use

eXaSkin is a medical device intended to be used as a bolus for the treatment of neoplastic skin lesions through radiotherapy. The product is designed to be applied to the irradiated area by qualified healthcare professionals to address anatomical irregularities and ensure precise delivery of the prescribed dose to the skin and underlying tissues during a radiation therapy treatment.

eXaSkin was evaluated using 6 MV photons but has not been assessed for use with 10 MV photons, protons, or orthovoltage X-rays.

eXaSkin Plus 150 and 225 is intended for general radiotherapy use.

eXaSkin Plus 650 is intended for use on breast tissue.

Comparison of Technological Characteristics with the Predicate and Reference Devices

The subject device has the same or similar intended use, indications, principle of operation, technological and material characteristics as the predicate device, .decimal Bolus (K211511), and reference device, Superflab (K812983). Comparisons of the predicate, reference, and subject devices can be found in Table 1:

Table 1 Comparison of the Subject, Primary Predicate, and Reference Devices

	AnatGe eXaSkin Plus (Subject)	**.decimal Bolus (Predicate) *K211511***	**Superflab (Reference) *K812893***	**Discussion**
Regulation	892.5710, 892.5050	892.5710, 892.5050	892.1370	Same as .decimal Bolus
Classification	Radiation therapy beam-shaping block, Medical charged-particle radiation therapy system.	Radiation therapy beam-shaping block, Medical charged-particle radiation therapy system.	Nuclear anthropomorphic phantom.	Same as .decimal Bolus

Product Code	IXI, MUJ	MUJ, IXI	IYP	Same as .decimal Bolus
Class	II	II	I	Same as .decimal Bolus
OTC or Rx	Rx	Rx	Rx	Same
Indications for Use	eXaSkin is a medical device intended to be used as a bolus for the treatment of neoplastic skin lesions through radiotherapy. The product is designed to be applied to the irradiated area by qualified healthcare professionals to address anatomical irregularities and ensure precise delivery of the prescribed dose to the skin and underlying tissues during a radiation therapy treatment. eXaSkin was evaluated using 6 MV photons but has not been assessed for use with 10 MV photons, protons, or orthovoltage X-rays. eXaSkin Plus 150 and 225 is intended for general radiotherapy use. eXaSkin Plus 650 is intended for use on breast tissue.	The decimal Bolus product is a solid piece of material (rigid or rubber-like) that will be placed on the skin of a patient with the intended use and primary purpose of helping control the dose received by that patient when undergoing radiation therapy treatment. decimal Bolus devices are designed by radiation therapy professionals to a unique shape that is specific to each patient being treated. The device is intended to modify the dose delivered during a radiation therapy treatment. As this product is a simple general purpose bolus device, the intended patient population and indications for use are quite broad. The most common indications for use are for the treatment of patients receiving radiation therapy, which encompasses a wide range of potential disease types and locations. As such, these devices will be required to have a wide range of potential shapes, sizes, and material properties and each device must be	This product is single-use only, and single patient use only. Do not Reprocess and dispose of this product after use. This product is to be used to increase the targeted radiation dose during photon and electron treatment by providing scattering of the beam and build-up of the radiation dose at the skin surface.	Different The .decimal Bolus is made of a solid material that is custom designed to be a unique shape specific to the patient being treated, while the eXaSkin is a putty designed to harden in a unique shape specific to the patient that it is applied to. This difference in material does not constitute a new intended use because the different materials used in each device serve the same intended purpose. Both the eXaSkin and .decimal Bolus are intended to control the radiation dose delivered to patients during radiation therapy treatments via a material that will be fit to the patient's skin. The difference does not raise different questions of substantial equivalence. Biocompatibility testing was performed, supporting substantial equivalence of skin-safe material. Data from bench testing for the eXaSkin supports substantial equivalence. Similar to the eXaSkin moldable putty, the Superflab is made of a moldable, elastic material that can conform to the contours of the patient. Testing was performed comparing the performance of the

		tested and approved by the radiation therapy professional prior to use on a patient.		eXaSkin and Superflab (see Performance Testing section for more details), and performance was found to be substantially equivalent.
Materials	Putty and Catalyzer	100% Silicone	Synthetic oil gel including PVC Resin 01 and Plasticizer 34	Different The eXaSkin, predicate, and reference device are all constructed from skin-safe materials and are used to control the dose delivered to patients undergoing radiation therapy treatments via fitting to the contours of a patient's skin. Unlike the predicate, the eXaSkin is not custom-made solid material, but a moldable putty. The difference in material does not raise concerns regarding substantial equivalence and the eXaSkin has been proven biocompatible via biocompatibility testing.
Material Characteristics	Skin-safe, moldable material	Skin-safe, solid piece of rubber-like, flexible material	Skin-safe, moldable material	Different The eXaSkin, predicate,

				and reference device are all constructed from skin-safe materials and are used to control the dose delivered to patients undergoing radiation therapy treatments via fitting to the contours of a patient's skin. Unlike the predicate, the eXaSkin is not custom-made solid material, but a moldable putty. This difference in material characteristics does not raise different questions of substantial equivalence of the eXaSkin has been proven through literature and testing.
Patient Contact	Direct skin	Direct skin	Direct skin	The eXaSkin, predicate, and reference device are all placed directly on patient skin, but the eXaSkin has a contraindication for being used on open wounds. This difference does not raise different question related to the substantial equivalence of the device.
Use Environment	Radiotherapy clinic	Radiotherapy clinic	Radiotherapy clinic	Same
Patient Population	Patients undergoing radiation therapy treatment	Patients undergoing radiation therapy treatment	Patients undergoing radiation therapy treatment	Same

Biocompatibility

Biocompatibility testing was conducted on representative final manufactured samples in accordance with ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”. Test results are summarized in Table 2:

Table 2 Summary of Biocompatibility Testing Conducted on the eXaSkin Plus

Biocompatibility Testing Requirements	Test Method	Material	Acceptance Criteria	Test Result
ISO 10993-5 – Tests for in vitro cytotoxicity	Direct Contact	eXaSkin Plus	Not cytotoxic	Not cytotoxic
ISO 10993-10 – Tests for skin sensitization	Assessment of sensitizing properties on albino guinea pigs, Maximisation test according to Magnusson and Kligman	eXaSkin Plus	Non-skin sensitizer	Non-skin sensitizer
ISO 10993-23 - Tests for irritation	Assessment of acute local tolerance and general tolerance on white rabbits	eXaSkin Plus	Not an irritant	Not an irritant

Performance Data

Bench

Non-clinical validation testing was performed to demonstrate substantial equivalence of the device. The following tests were performed:

Test	Objective	Reference	Pass/Fail Criteria	Results
Mixing Time	Evaluate the time required for two or more components to mix homogeneously in a mixture, process, or product.	ISO 4823: 2021	30 s	Pass
Setting time at 35°C	Evaluate the time it takes for a material, typically in paste or liquid form, to transition from a fluid or plastic state to a solid or rigid state.	2100-AM QC-023	Catalyzer: 190 - 320 s Putty: 210 - 75s	Pass
Hardness after 8 minutes	Evaluate the hardness of a material after 8 minutes (early curing stage).	2100-AM QC-013	Catalyzer: 20 - 34 Shore A Putty: 60 - 75 Shore A	Pass
Hardness after 1 hour	Evaluate the hardness of a material after 1 hour.	2100-AM QC-013	Catalyzer: 24 - 35 Shore A Putty: 65 - 77 Shore A	Pass

Consistency	Evaluate the material's ability to maintain a specific viscosity or fluidity under certain conditions.	2100-AM QC-011	Catalyzer: 33-44 mm Putty: ≤ 35 mm	Pass
Mixed Material	Ensure that the mixture of materials has reached the expected homogeneity and to assess how the characteristics of the combined material behave under specific conditions.	2100-AM QC-004	Homogeneous and free of extraneous matter	Pass
Visual aspect	Evaluates the external appearance of the material to ensure it meets the quality standards in terms of aspect.	2100-AM QC-004	Homogeneous and free of extraneous matter	Pass
Color	evaluates the external appearance of the material to ensure it meets the quality standards in terms of color.	2100-AM QC-004	Purple	Pass
Odor	evaluates the external appearance of the material to ensure it meets the quality standards in terms of odor.	2100-AM QC-005	Catalyzer: Mint Putty: Vanilla	Pass
Working Time	Evaluates the time during which the material maintains its workability properties before it begins to change or harden significantly.	ISO 4823: 2021	75 s	Pass
Elastic recovery	Evaluates the material’s ability to recover its original shape after being deformed under load and then released.	ISO 4823: 2021	≥ 96.5%	Pass
Strain-in-compression	Evaluates deformation (or change in dimensions of the material) when a compressive force is applied until a specific point.	ISO 4823: 2021	0.8 - 20%	Pass
Detail reproduction	Assess the material’s ability to accurately reproduce fine details or characteristics of a mold or reference surface.	ISO 4823: 2021	75 µm	Pass
Compatibility with gypsum	Evaluates the interaction between the material and the gypsum used in impression or manufacturing processes.	ISO 4823: 2021	75 µm	Pass
Linear	Evaluate the material’s dimensional	ISO 4823: 2021	≤ 1.5%	Pass

dimensional change 24h	stability after a 24-hour period. It measures whether the material undergoes expansion or contraction in its linear dimensions (length, width, or height) during the first 24 hours after its curing or formation process.			
Material Properties	Evaluate eXaSkin, a novel high-density bolus alternative to commercial tissue-equivalent Superflab, for 6MV photon-beam radiotherapy.	N/A	Improved adaptation to phantom's surface over Superflab Full dosage achieved (agreement within 1% of calculations)	Pass
Dose Distribution and Radiation Attenuation	Determine dosimetric accuracy for calculating photon dose distribution in the presence of eXaSkin bolus.	N/A	Agreement in dose calculation - 3mm/3% Improved surface dose	Pass
Usability	Evaluate eXaSkin to commercial tissue-equivalent Superflab, for 6MV photon-beam radiotherapy.	N/A	N/A	Pass

Animal

No animal or clinical testing was performed in support of this submission.

Clinical

No animal or clinical testing was performed in support of this submission.

Substantial Equivalence Conclusion

Based on the comparison of indication of use, material characteristics, technological features, and principle of operation, and conclusions drawn from performance testing to demonstrate substantial equivalence (SE), the AnatGe eXaSkin Plus is substantially equivalent to the predicate device.