October 17, 2025

Electrogenics Labs, Ltd
Grant Palmer
Head of QA/RA
Suite 1, Level 10
76 Berry Street
North Sydney, NSW 2060
Australia

Re: K250911
Trade/Device Name: MOSkin Radiation Measurement System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: NZT,IYE
Dated: March 26, 2025
Received: March 26, 2025

Dear Grant Palmer:

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,

Digitally signed by Michael D. O'hara -S
Date: 2025.10.17 13:39:21 -04'00'

For

Lora Weidner
Assistant Director
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)*
K250911

Device Name

MOSkin Radiation Measurement System

Indications for Use *(Describe)*

The MOSkin radiation measurement system intended use is a dosimeter to measure radiation dose delivered by a radiation source to the location of an Radiation Dosimeter (RD) sensor on the patient in a clinical use environment. The system is intended for the verification of the output of radiation producing devices. The output of the system is not used to directly adjust the radiation dose to the patient.

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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510(k) Summary K250911

Submission Date: March 26, 2025
Summary Prepared Date: October 09, 2025

Submitter Information:

Submitted By: Grant Palmer
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Device Information:

Trade Name: MOSkin Radiation Measurement System
Common Name: Dosimetry System

Classification Name: 21 CFR 892.5050 Medical Charged-particle radiation therapy system

Device Classification: Class II

Product Code: NZT, IYE

Predicate Device(s): Portable Dosimeter, K092285
Best Medical Canada, Ltd. Class II,
Product Code IYE
21 CFR 892.5050 Medical Charged-particle radiation therapy system

Device Description: The Electrogenics Laboratories Ltd MOSkin Radiation Measurement System consists of the following components to provide secondary verification of dose from various radiotherapy and diagnostic imaging devices:

- MOSFET (Si-based metal-oxide-semiconductor field-effect transistor) Dosimeter (RD) to record radiation during radiation exposure.
- Reading device (HUB) for reading the radiation dose recorded by the dosimeter.
- MOSkin Software Application, a simple software tool that the user interacts with for radiation dose calculation, dose reporting, managing and storing data.

Indications for Use: The MOSkin radiation measurement system intended use is a dosimeter to measure radiation dose delivered by a radiation source to the location of a Radiation Dosimeter (RD) sensor on the patient in a clinical use environment. The system is intended for the verification of the output of radiation producing devices. The output of the system is not used to directly adjust the radiation dose to the patient.

Comparison to Predicate: The intended use of the predicate device (K092285) is: "To provide dosimetry or to detect the dose delivered to a patient during therapeutic radiation procedures. The system is intended for the verification of the output of radiation producing devices."
The intended use of the MOSkin System is: "The MOSkin radiation measurement system intended use is a dosimeter to measure radiation dose delivered by a radiation source to the location of an RD sensor (RD) on the patient in a clinical use environment. The system is intended for the verification of the output of radiation producing devices. The output of the system is not used to directly adjust the radiation dose to the patient."
The two key points of both statements is that each system provides:
1) dosimetry for the delivered dose of radiation
2) the system is intended to provide verification of delivered dose.
Therefore, although the text is slightly different from the predicate, the intended use remains the same between the proposed device and predicate device (capturing and displaying radiation dose) and the proposed differences in indications are for clarity and do not have impact on safety or effectiveness.
The MOSkin System utilizes a MOSFET (Si-based metal-oxide-semiconductor field-effect transistor) as the measurement technology for determining the radiation dose delivered to a patient. The incident therapeutic radiation changes the electrical characteristics of MOSFET, specifically the threshold voltage, which can be measured. By measuring the threshold voltage before and after radiation treatment, the radiation

dose can be calculated. The predicate device (K092285) uses the same measurement technology and principle of operation as the MOSkin System.

The MOSkin System provides greater flexibility for treating physicians by providing twice the measure dosage range (up to 400 cGy vs 200 cGy) compared to predicate, while maintaining similar dose accuracy and angular dependence, across a similar range to therapies.

The dosimeter of the MOSkin System is single-use, removing the need for dosimeter disinfection and reducing the risk of cross-contamination between patients. This configuration also provides an over-all smaller dosimeter package, potentially facilitating a greater ease of use. The tablet interface, versus the desktop computer of the predicate, provides and smaller benchtop footprint and a degree of mobility.

The proposed device therefore employs the same fundamental scientific technology, and any differences do not raise different questions of safety or effectiveness. The device contains several advantages for use over the predicate including a wider range of measured radiation dose, wireless technology, smaller size and flexible user interface.

Feature & Specification	Electrogenics MOSkin	Best Medical Portable Dosimeter	Comparison
Indication for Use	The MOSkin radiation measurement system intended use is a dosimeter to measure radiation dose delivered by a radiation source to the location of a Radiation Dosimeter (RD) sensor on the patient in a clinical use environment. The system is intended for the verification of the output of radiation producing devices. The output of the system is not used to directly adjust the radiation dose to the patient.	To provide dosimetry or to detect the dose delivered to a patient during therapeutic radiation procedures. The system is intended for the verification of the output of radiation producing devices.	Similar
Measurement Technology	Metal–Oxide–Semiconductor Field-Effect Transistor (MOSFET	Metal–Oxide–Semiconductor Field-Effect Transistor (MOSFET	Same
Principle of Operation	Threshold voltage change proportional to radiation dose	Threshold voltage change proportional to radiation dose	Same

Feature & Specification	Electrogenics MOSkin	Best Medical Portable Dosimeter	Comparison
Dose Range	Up to 400 cGy	Up to 200 cGy	MOSkin has superior range
Accuracy	±5 cGy (dose <100 cGy) ±5 % (dose ≥ 100 cGy)	±3 % (at 20 cGy) ±2 % (at 200cGy)	Similar
Angular dependence	+/-5 % of fitted angular offset curve at angles 0-180-360°.	±2 % for 360°	Similar
Width of Dosimeter	6 mm	2.5 mm	MOSkin provides a smaller overall dosimeter envelope, increasing ease and flexibility of use
Thickness of Dosimeter	0.3 mm	0.3 mm	
Length of Dosimeter	30 mm	200 mm	
Volume	~54 mm^3	~150 mm^3	
Number of Simultaneous Dosimeters Supported	Up to four	Up to five	Similar
Reusable vs single use	Single use dosimeter	Reusable dosimeter	Removes requirement for sterilization of dosimeters
Surface/Skin Dose Measurements	Yes	Yes	Same
Dose Report for Patient Files	Advanced patient reports in PDF format	Advanced patient reports in MSWord, Excel and PDF to R&V systems	Both provide reports in human readable format
Dosimeter Connection: Wireless vs Wired	Wireless	Wired	Wireless provides greater flexibility in use
Connection during Treatment	Wireless	Wired	Wireless provides greater flexibility in use
Dosimetry Display	Data transfer using Bluetooth technology to tablet-based MOSkin Monitor	Data transfer using Bluetooth technology and on-line readout from a remote PC	Similar
User Interface: Tablet vs PC	Tablet	PC	Tablet provides similar user experience with greater flexibility
Calibration	Factory calibrated Physicists can create custom calibrations to match their settings	Determined by physicists to match their settings	MOSkin provides ease of use in a “straight from the box” case.

Feature & Specification	Electrogenics MOSkin	Best Medical Portable Dosimeter	Comparison
Power	Built-in rechargeable Battery Operable while charging	AA rechargeable Battery	Similar
Applications	TBI/ Central Dose High Dose Fluoroscopy	TBI/ Central Dose High Dose Fluoroscopy	Same

Performance Testing:

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

Biocompatibility testing

Evaluation included consideration of physical characteristics, chemical characteristics, manufacturing processes and biological testing. As per ISO 10993-1:2018 the device is in contact with intact skin, only., and the contact duration is B – Prolonged (1-30 d).

For devices in limited contact with intact skin ISO 10993-1:2018 Table A.1 (and FDA Guidance) indicates the following endpoints should be evaluated in the risk assessment. Evaluation may include review of existing data, additional endpoint specific testing, or a rationale of why the endpoint assessment does not require an additional data set. Relevant subparts of ISO 10993 which provide specific guidance are identified and annotated next to the relevant biological evaluation endpoint.

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Irritation (ISO 10993-23:2021)

All testing passed, with no deviations.

Based on this testing, the MOSkin Radiation Dosimeter is not cytotoxic, an irritant or a sensitizer. It is biocompatible for the intended use and the indications for use.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted, consisting of the Radiation Dosimeter, MOSkin HUB and MOSkin Monitor. The system complies with the IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AMD1 (2012) + AMD2 (2020); EN 60601-1:2006 + AC1:2010 + A11:2011 + A12:2014 + AC2:2016 + A2:2021; CAN/CSA-C22.2 No. 60601-1:14; ANSI/AAMI ES60601-1:2005 + A1:2012 +A2:2021, EN 62479:2010 and JIS T 0601-1:2023 standards for safety and the IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 and CSA-C22.2 No.60601-1-6:2011/A2:2021standardsfor EMC.

The system was also tested for compliance to 47 Code of Federal Regulations Part 15 – Radio Frequency Devices and ETSI EN 300 328 V2.2.2: Compliance for 2.4 GHz ISM Band Devices. The system passed all testing.

Usability Studies

The MOSkin System underwent usability four usability evaluations, three (3) formative and one (1) summative and summarized below.

Test		Result
Formative Evaluation	01	This study evaluated the workflow of using the MOSkin System in the radiation treatment of simulated patients with two (2) participants, both Radiation Therapists. The evaluation resulted in several recommended improvements to the system for ease of use and clarity. There were no unresolved usability problems that could affect patient, users or environmental safety.
	02	This study evaluated the workflow of using the MOSkin System in the radiation treatment of simulated patients with two (2) participants, one Medical Physicist and one Radiation Therapist. The evaluation resulted in several recommended improvements to the system for ease of use and clarity. There were no unresolved usability problems that could affect patient, users or environmental safety.
	03	This study evaluated the workflow of using the MOSkin System in the radiation treatment of simulated patients and the administrative functions of the system. There was a total of six (6) participants, two (2) administrators, and four (4) operators. The evaluation resulted in several recommended improvements to the system for ease of use and clarity. There were no unresolved usability problems that could affect patient, users or environmental safety.
Summative Evaluation		This study evaluated the workflow of using the MOSkin System in the radiation treatment of simulated patients and the administrative functions of the system. There was a total of 18 participants, eight (8) administrators, and ten (10) operators. The evaluation resulted in several recommended improvements to the system for ease of use and clarity. There were no unresolved usability problems that could affect patient, users or environmental safety

The study reports were then evaluated and certified to comply with IEC 60601-1-6 by TÜV SÜD PSB Pte Ltd.[8]

The MOSkin System has therefore, been successfully evaluated for usability by potential users. These evaluations did not discover any unresolved usability problems that could affect patient, users or environmental safety.

Mechanical testing

The MOSkin System underwent the following mechanical testing:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2021)
- Irritation (ISO 10993-23:2021)
- Lid reliability
- Repeatability
- RD Continuity
- Force on RD
- Port Reliability - RD Connection reliability (ref [PRD])
- On/Off push force
- Ability to open DAT Lid
- RD Adhesive Strength

- RD Packaging opening force
- RD Storage
- RD Protection
- Chemical Resistance

All mechanical testing passed and demonstrated that the MOSkin System is reliable and mechanically suited for use.

Environmental Transport

The ability of the MOSkin System be shipped without compromising patient, user or environmental safety was evaluated to ISTA 3A. Representative devices were tested for function before and after environmental and transport simulations. The MOSkin System has PASSED environmental transport testing according to ISTA 3A.

Atmospheric Pressure

The tolerance of the MOSkin System to the atmospheric pressure range that the system may be subjected to during transport, storage and use was evaluated. The evaluation concluded that the MOSkin System can operate within specification when subjected to atmospheric pressures within the range 78 kPa to 114 kPa.

Electrical Verification

Each electrical system requirement for the MOSkin was tested. The MOSkin System was found to meet all electrical requirements.

Storage Life

The components and materials within the MOSkin System were evaluated for any degradation due to the labelled storage conditions. The report concludes that the MOSkin System is unlikely to be degraded due to appropriate storage.

Systems have been evaluated after six-month of storage. All devices passed testing

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." All software testing passed, and the software was found to meet all requirements.

Cybersecurity

This cybersecurity report confirms that the Cybersecurity Management Plan has been successfully implemented for MOSkin. The applied security measures align with FDA requirements and additional cybersecurity frameworks. Security testing validated the robustness of controls, and any potential improvement identified were addressed appropriately.

The overall impact of wireless communication failure in this device has been assessed as negligible, meaning that any disruption in BLE or Wi-Fi functionality would result only in inconvenience or temporary discomfort, with no foreseeable risk to patient safety or device operation.

System Performance

The MOSkin System underwent a series of tests to evaluate the requirements related to the clinical performance. All testing was completed under simulated use conditions. The tested requirements were:

- Reliably & accurately measure the radiation dose received by the sensor during patient radiotherapy treatments or dummy/phantom trials.
    - Dose range 10-400 cGy
    - Accuracy +/-5 % at doses => 100 cGy
    - Accuracy within +/-5 cGy at doses < 100 cGy
- Accurate skin dose radiation measurement at a water equivalent depth of <0.15 mm.
- MOSkin RD provides dose accuracy measurement of +/-5 % compared with an independent calibrated radiation source in specific clinical test scenarios.
- RD and MOSkin system shall provide overall dose measurement with <1.0 % fading over 2 hours.
- RD and MOSkin System shall be characterized at a range of non-perpendicular Linac beam angles. All MOSkin RD dose measurements shall be +/-5 % to a fitted angular response curve at each angle setpoint.

The MOSkin System passed all requirements related to clinical use.

Animal Studies

Animal studies were not necessary to support substantial equivalence of the proposed device to the predicate device.

Clinical Studies

Clinical studies were not necessary to support substantial equivalence of the proposed device to the predicate device.

Summary

Based on the clinical performance as documented in the pivotal clinical study, the MOSkin System was found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusion: In conclusion, the tests conducted, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the MOSkin System meet applicable requirements and standards for the safety and effectiveness of the device for its intended use. The intended use and fundamental technology are the same between the subject and predicate devices. There are some

differences in the indications for use and technological characteristics between the predicate and subject devices, but those differences allow for the MOSkin System to have additional use capabilities and improv ed usability. The testing and validation activities conducted demonstrate that any differences between the devices do not raise new or different questions of safety or effectiveness as compared to the predicate device. Therefore, the MOSkin System is substantially equivalent to the predicate device.