June 21, 2024

Walgreen Health Solutions, LLC
% Yolanda Smith
Consultant
Smith Assoicates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K233096
Trade/Device Name: PRESSUREALERT® Pressure Monitoring System
Regulation Number: 21 CFR 880.2400
Regulation Name: Bed-Patient Monitor
Regulatory Class: Class I
Product Code: SBO
Dated: May 20, 2024
Received: May 21, 2024

Dear Yolanda Smith:

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.

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,

David Wolloscheck

David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
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OHT3: Office of Gastrorenal, ObGyn,
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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)*
K233096

Device Name
PRESSUREALERT® Pressure Monitoring System

Indications for Use *(Describe)*
The PRESSUREALERT® Pressure Monitoring System monitors the activity of patients who are susceptible to pressure ulcers by measuring pressure at various points of the body. It allows healthcare providers to execute an individualized turn management plan for each patient by continuously monitoring pressure on various points of the body of each patient. The PRESSUREALERT® Pressure Monitoring System provides alerts when patient activity deviates from the pressure prevention parameters set for by the healthcare providers. The device is intended for use in medical, nursing, and long-term care facilities including independent living, assisted living, and rehabilitation facilities.

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.

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510(k) Summary
K233096

Name:	Walgreen Health Solutions, LLC
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Contact Person:	Dawn Bolles Regulatory Specialist
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2. Date Summary was prepared: June 18, 2024

3. Device Information:

Trade Name:	PRESSUREALERT® Pressure Monitoring System
Common Name:	Bed-patient activity monitoring system
Classification Name:	Bed-patient monitor
Review Panel:	General Hospital
Class:	Class I
Product Code:	SBO
CFR Regulation:	21 CFR 880.2400

4. Predicate Device

	Manufacturer	Trade Name	510(k) Number	Product Code
Primary Predicate	Leaf Healthcare Incorporated	Leaf Patient Monitoring System	K141877	KMI

5. Product Description

The PRESSUREALERT® Pressure Monitoring System is composed of a wireless pressure sensing dressing assembly as part of a system supported by the PRESSUREALERT® Management Software for providing a warning to the healthcare provider that soft tissue pressure has exceeded a predetermined level that, over a period of

time, would necessitate that the patient should be moved to prevent or at least reduce the risk of soft tissue damage.

The PRESSUREALERT® Pressure Monitoring System functions as a pressure monitoring system with the primary function to monitor a patient that is laying down on their back or otherwise in a position that may result in the patient's weight applying pressure to an area of the patient's body that is susceptible to pressure ulcers/injuries, such as soft tissue overlying a bony prominence.

The dressing assembly, with the enclosed pressure sensing sensor, is applied on the patient's body that is susceptible to damage from soft tissue pressure. The identified areas are referred to as "at-risk" in the instructional documentation and intended use and include up to eleven (11) sites defined as the upper spine, head-skull, hip (right or left), Ischia (right or left), heels and elbows (right or left), and sacrum. (See Product Comparison Table in Section 7)

The material components of the PRESSUREALERT® Pressure Monitoring System, and described in detail in the Device Description section, includes:

i. PRESSUREALERT® Segmented Oval Dressing
ii. PRESSUREALERT® Round Dressing
iii. PRESSUREALERT® Sacral Dressing
iv. PRESSUREALERT® Oval Sensor
v. PRESSUREALERT® Round Sensor

6. Indications for Use

The PRESSUREALERT® Pressure Monitoring System monitors the activity of patients who are susceptible to pressure ulcers by measuring pressure at various points of the body. It allows healthcare providers to execute an individualized turn management plan for each patient by continuously monitoring pressure on various points of the body of each patient. The PRESSUREALERT® Pressure Monitoring System provides alerts when patient activity deviates from the pressure prevention parameters set for by the healthcare providers. The device is intended for use in medical, nursing, and long-term care facilities including independent living, assisted living, and rehabilitation facilities.

7. Predicate Product Comparison Table

Attributes	Subject Device	Predicate Device	Comments
510(k) Number	K233096	K141877	
Device Name	PRESSUREALERT® Pressure Monitoring System	Leaf® Patient Monitoring System	
Manufacturer	Walgreen Health Solutions, LLC	Leaf Healthcare, Inc.	
Class	Class I	Class I	Same
Classification Regulation	21 CFR §880.2400	21 CFR §880.2400	Same
Regulation Name	Bed-Patient Monitor	Bed-Patient Monitor	Same
Indications for Use	The PRESSUREALERT® Pressure Monitoring System monitors the activity of patients who are susceptible to pressure ulcers by measuring pressure at various points of the body. It allows healthcare providers to execute an individualized turn management plan for each patient by continuously monitoring pressure on various points of the body of each patient. The PRESSUREALERT® Pressure Monitoring System provides alerts when patient activity deviates from the pressure prevention parameters set for by the healthcare providers. The device is intended for use in medical, nursing, and long-term care facilities including independent living, assisted living, and rehabilitation facilities.	The Leaf Patient Monitoring System monitors the orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. The Leaf Patient Monitoring System provides alerts when patient orientation or activity deviates from parameters set by healthcare providers. The device is intended for use in medical, nursing, and long-term care facilities, including independent living, assisted-living and rehabilitation facilities.	Similar for use in the prevention of pressure ulcer formation and execution of individualized turn management patient plans. The subject device can be placed on multiple parts of the body as compared to the predicate device which is placed in only 1 location as described in (Section 8) The Discussion of Technological Differences, Body Site Location and the differences raises no new issues of safety and effectiveness.
Principle of Operation	Wearable pressure sensor (inserted into a dressing and attached to patients' skin) functions to provide monitoring of selected "at risk" body locations and alarm if meets pressure level thresholds related to pressure ulcer formation. Table pressure site color coding corelates to	Wearable sensor attached to patients' skin and a display monitor for turn status and alerts. Wearable sensor that provides reminders and tracking of patient repositioning and turning in order to prevent pressure ulcer formation.	Similar, supports patient repositioning protocol. The Discussion of Technological Differences (Section 8), Body Site Location, refers to the differences in the operation of the

Attributes	Subject Device	Predicate Device	Comments
	different pressure and alarm when threshold met. Bedside tablet and remote monitoring provide reporting on pressure events and repositioning reporting to support effective patient repositioning protocol.		subject device operations and raises no new issues of safety and effectiveness.
Intended Population	The PRESSUREALERT® Pressure Monitoring System is not intended for use with patients under the age of 18, pregnant women, or the morbidly obese (Class 3, BMI 40 or greater). Safe use for patients under the age of 18, pregnant women, and the morbidly obese has not been established.	The Leaf Patient Monitoring System has not been tested on women who are pregnant or breastfeeding, so the risks to unborn fetuses and nursing children are unknown. Safety and effectiveness for use by pregnant women and children (under the age of 18) has not been established.	Similar, the predicate device indication does not include the morbidly obese potentially due to the placement location on the patient (single site, chest). The subject device can be utilized on up to 11 body site locations and the morbidly obese require special repositioning protocol, staff, and equipment that could interfere with the sensor. This contraindication raises no new issues of safety and effectiveness.
Intended Use Environment	The device is for use in professional healthcare facilities only including independent living, assisted living, and rehabilitation facilities.	The device is intended for use in medical, nursing, and long-term care facilities, including independent living, assisted living, and rehabilitation facilities.	Same
Prescription	Yes	Yes	Same
Single Use	Sensor Dressing Only (Sensor No)	No	Same
Sterile	No	No	Same
Single Patient – Multiple Use	Sensor Only	Yes (on label of Sensor)	Same
Sensor Size	Round Sensor - placed in round or sacral dressing foam pocket: Oval Sensor - placed into oval segmented dressing foam pocket:	Sensor Single 1.8” x 2.0”,	The subject device has a larger contact area. The adhesive, skin contact surface, for both the predicate and subject device utilize a

Attributes	Subject Device	Predicate Device	Comments
			medical grade adhesive.
Skin Contact Material	Silicone Sensor Dressing skin adhesive material	• Patient Sensor Skin Adhesive Material	Same
Body Non-Skin Contact Material	Foam Pressure Sensor Pocket for containing sensor	• Thermoplastic vulcanizate Sensor Cover	Different Subject device allows sensor cover (dressing) to be changed as necessary. Refer to the Discussion of Technological Differences (Section 8), Body Non-skin Contact Material.
System Configuration	The PRESSUREALERT® Pressure Monitoring System is comprised of: • PRESSUREALERT® (Patient) Pressure Sensors (round or oval) • PRESSUREALERT® Oval Segmented Dressings (for use with oval sensors) • PRESSUREALERT® Round Dressings (for use with round sensors) • PRESSUREALERT® Sacral Dressings (for use with round sensors) • PRESSUREALERT® Management Software (Medical Application for Facilities' User Interface (Android Tablet) and Network Server Software (Web- portal and Cloud-based secure data storage)	The Leaf Patient Monitoring System is comprised of: • Leaf Patient Sensors • Leaf Relay Antennas • Leaf USB Transceiver(s) (Mesh network) Leaf Patient Monitoring Software and User Interface that can be viewed on a monitoring station.	Similar technology for Primary Predicate in the use of a sensor(s) that are wireless, lithium battery operated, utilize RF wireless technology for data transfer, incorporate a user interface for monitoring, data storage, remote access to patients' data and report configuration. Refer to Discussion of Technological Differences in (Section 8), Body Site Location and Mechanism of Use.
Patient Sensor Power source	Internally Powered	Internally Powered	Same
Patient Sensor Wireless Transmission Frequency	2.4 GHz	2.4 GHz	Same
Electrical Voltage – Power Supply (Patient Sensor)	3 VDC	3 VDC	Same

Attributes	Subject Device	Predicate Device	Comments
Patient Sensor Applied Part Type	Patient Sensor Applied Part Type BF	Patient Sensor Applied Part Type CF	Similar, CF based on location over heart (cardiac application), the subject device is not placed directly over the heart. The subject device can be placed up to 11 locations as discussed in the Discussion of Technological Differences (Section 8), Body Site Location (there are 11 locations including: left/right hips, left/right ischium (buttocks), left/right heels, skull, upper spine prominence, left/right elbows, and sacrum (tailbone)) and is not located over the heart. This difference raises no new issues of safety and effectiveness.
Electromagnetic Emissions	Compliant with Part 15 of FCC Rules	Compliant with Part 15 of FCC Rules	Same
Alerts	Yes	Yes	Same
Patient Sensor Wireless Transmission Protocol	Utilizes wireless technology.	Utilize wireless technology.	Same
Biocompatibility (Silicone Foam Dressing) un-breached skin only	ISO 10993-1	Though the silicone adhesive material used in the Leaf Patient Sensor is commonly used in other healthcare products and has a well-established safety profile, an allergic reaction to the adhesive is possible. If a patient experiences a rash, skin redness, itching, or swelling in the area where the Leaf Patient Sensor was applied, this may be a sign of an allergic reaction and	Same, both the subject device and primary predicate use a silicone adhesive material (skin contact) commonly used in the healthcare industry as described in the Discussion of Technological Differences, (Section 8), Body Non-skin Contact Material. Biocompatibility data is available for

Attributes	Subject Device	Predicate Device	Comments
		should be evaluated immediately by the patient's doctor or other member of their care team.	adhesive used in the subject device.
Product Stability/Life of the Device	• Sensor – up to 25 days after activation. 1-year if not activated. Dressings – 2-years if package unopened or adhesive not exposed.	• The Leaf Patient Sensor is designed to work until the battery is depleted, which is typically up to 21 days. • The device is designed for single patient multiple use. If the sensor needs to be removed from a patient temporarily follow instructions on "Removing the Leaf Patient Sensor", to reapply the sensor follow instructions for "Re-Applying the Patient Sensor. • There are no parts that need to be replaced. The Patient Sensor is working properly if it functions as described in this booklet.	Leaf and PRESSUREALERT® activated battery life within a similar range of 21 to 25 days as described in the Discussion of Technological Differences (Section 8), Battery Life.
Report Data	The following options are available: <u>Report type:</u> • Patient Info • Pressure Ulcer status (optional data report) • Events status (Pressure events) • Reposition status (Turning protocol reporting and pressure relief reporting) • Alarm Response status <u>Patient information:</u> • Required (MRN).	• Report Generated Date and time. • Patient Information (Patient Name, first and last, MRN, start date, end date, patient status, unit, room) • Turning protocol settings • Summary of turns, monitoring time, time upright, time prone, patient movement Total time on left, back,	General patient information input – same. • Leaf reports, and subject device can monitor patient turning / repositioning. • Subject device can also report additional pressure events outside of the facility standard turning protocol at

Attributes	Subject Device	Predicate Device	Comments
	• Patient First and Last Name, Age, Gender, existing Pressure Injuries, and location are all optional information. • Sensor(s) serial number and location on patient.	right, left upright, back upright, right upright, left semi prone, prone, right semi prone.	specific at- risk locations. In the Discussion of Technological Differences (Section 8), Body Site Location, the subject device monitors pressure between standard turning protocol.

8. Discussion of Technological Differences

Body Site Location – Location for the predicate device is a single location (chest). The subject device can be located on 11 different areas of the body and can report repositioning data. This difference raises no new issues of safety and effectiveness because of verification and validation of the software. The subject device detects activity via pressure changes; the predicate device detects activity via orientation changes with an accelerometer.

Mechanism of Use – The subject device, unlike the predicate, does not utilize USB relay / antennas mesh network with antenna. The subject device incorporates the latest wireless technology to accomplish the same data transfer and raises no new issues of safety and effectiveness.

Sensor Size – The subject device has a larger contact area compared to the predicate device, but the adhesive used in both devices is a medical grade commonly used in medical dressing. The sensor size difference raises no new issues of safety and effectiveness.

Non-skin Contact Material – Both the subject device and the predicate device provide a patient non-contact sensor by encapsulating the sensor inside a covered component that is attached to the patient's skin by use of a medical grade adhesive commonly used in medical dressings. The subject device non-contact sensor can be removed from the dressing to change the dressing as needed whereas the predicate sensor is sealed. The sensor non-skin contact differences raises no new issues of safety and effectiveness.

Battery Life – The subject sensor battery life, once activated, can be used up to 25 days and 1 year if not activated. The predicate sensor battery life, once activated, can be used up to 21 days, The difference between sensor battery life of the predicate and subject device 21 days and 25 days once activated raises no new issues of safety and effectiveness.

Non-Clinical Test Result Summary

The Product Comparison discussions of the technological differences, and the conclusions drawn from the non-clinical testing; those results demonstrate that the PRESSUREALERT® Pressure Monitoring System is substantially equivalent to the predicate device. Non-clinical testing included Ingress protection testing, drop testing, and battery life testing. Regarding the Ingress protection testing, the tests performed on the PRESSUREALERT® Pressure Sensors and Pressure Sensor Dressings included the IP4X 1 mm Sphere test and the IPX7 temporary water immersion test. There were no unexpected results, and the results of both tests were a "Pass".

The drop test required that the PRESSUREALERT® Pressure Sensors pass the

functionality parameters and have no visual signs of damage. Again, there were no unexpected results, and the test was given a "Pass". The battery life test for the Sensor's Lithium battery was performed and there were no unexpected results, and the sensor has a "Pass" for a calculated maximum storage battery life of 1 year and an activated operating life of 25 days. The battery life parameters were based on a maximum storage temperature of +70°C and an activated battery operating temperature range of +5°C to +40°C. The use of the worst-case temperature scenario was determined to be the basis for the recommended operating use and storage life. Finally, the third party non-clinical testing has shown that after extensive pressure sensor performance (activation pressure test) testing, the PRESSUREALERT® Pressure Monitoring System sensor attained the required threshold of 32 mmHg (equivalent to 43.5 g/cm^2).

9. Non-clinical Testing

- IEC 60601-1-2:2014+A1:2020, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests
    - CISPR 11:2015+A1:2016+A2:2019 - Limits and methods of measurement of radio disturbance, Characteristics of industrial, scientific, and medical radio frequency equipment
    - IEC 61000-4-2:2008 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test
    - IEC 61000-4-3:2010 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 3: Radiated, radiofrequency, electromagnetic field immunity test.
    - IEC 61000-4-8:2009 - Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 8: Power frequency magnetic field immunity test
- IEEE/ANSI C63.27-2021 – American National Standard for Evaluation of Wireless Coexistence
- AAMI TIR69 2017(R2020) - Risk management of radio-frequency wireless coexistence for medical devices and systems
- AIM 7351731 Rev. 3.00 (2021-06-04) – Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- FDA Guidance Document - Electromagnetic Compatibility (EMC) of Medical Devices (June 6, 2022) – Section J – Common Electromagnetic (EM) Emitters
- IEC TR 60601-4-2:2016 - Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC 62304:2006/A1:2006 Medical device software – Software life cycle processes – Medical Equipment Process Standard
- ISO 14971:2007+2019 Medical devices — Application of risk management to medical devices – Medical Equipment Management Standard.
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5 Biological evaluation of medical devices – Part 5 Tests for in vitro (cytotoxicity)
- ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for Irritation and Sensitization

In addition, the following system performance bench tests were conducted:

- Software verification
- Ingress Protection Testing
- Drop Tests
- Battery Life
- Pressure Sensor Performance Testing (Activation Pressure Test)

10. Clinical Studies

There were no clinical studies conducted.

11. Conclusion

Based on the Product Comparison Table (Section 7) and the discussions of the technological differences and non-clinical testing, the results demonstrate the PRESSUREALERT® Pressure Monitoring System is substantially equivalent to the predicate to assist in effective patient turning protocol and aid in the prevention of pressure ulcers.