DE NOVO CLASSIFICATION REQUEST FOR SEM SCANNER (MODEL 200)

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Pressure ulcer management tool. A pressure ulcer management tool is a prescription device intended for patients at risk of developing pressure ulcers. The device provides output that supports a user's decision to increase intervention. The device is an adjunct tool for pressure ulcer management that is not intended for detection or diagnostic purposes.

NEW REGULATION NUMBER: 21 CFR 876.2100

CLASSIFICATION: Class I (Exempt from premarket notification review, subject to limitations in 21 CFR 876.9)

PRODUCT CODE: QEF

BACKGROUND

DEVICE NAME: SEM Scanner (Model 200)

SUBMISSION NUMBER: DEN170021

DATE DE NOVO RECEIVED: April 3, 2017

SPONSOR INFORMATION:

Bruin Biometrics, LLC
10960 Wilshire Blvd., # 950
Los Angeles, CA 90024

INDICATIONS FOR USE

The SEM Scanner (Model 200) is intended to be used by healthcare professionals as an adjunct to standard of care when assessing the heels and sacrum of patients who are at increased risk for pressure ulcers.

LIMITATIONS

The sale, distribution, and use of the SEM Scanner (Model 200) are restricted to prescription use in accordance with 21 CFR 801.109.

WARNING: The standard of care should be followed for reducing the risk of developing pressure ulcers. Readings from the SEM Scanner 200 can be used to support increased intervention, but should never be to the basis for decreasing intervention.

WARNING: This device is not intended to be used for detecting or diagnosis of pressure ulcers.

WARNING: To prevent the spread of infection, the SEM Scanner 200 should be properly cleaned and disinfected according to the instructions provided in this Instructions for Use after it is used on a patient.

WARNING: Should the device come in contact with non-sterile surfaces (for example, if it falls on the floor) it should be cleaned and disinfected before obtaining another patient reading.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

RATIONALE FOR EXEMPTION

Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does meet these criteria and, therefore, premarket notification is not required for the device.

General controls provide reasonable assurance of safety and effectiveness, if device manufacturers comply with such requirements, which includes current good manufacturing practice requirements (21 CFR part 820), including design controls (820.30) due to the inclusion of software, and general labeling (21 CFR part 801). Examples exceeding the limitations of exemption could include indications for diagnostic purposes, clinical decision making, early detection of pressure ulcers, measurement of sub-epidermal moisture, supporting a user's decision to decrease intervention, or the device operates using a different fundamental scientific technology.

DEVICE DESCRIPTION

The SEM Scanner (Model 200) is a hand-held, portable device that consists of a single electrode sensor, an integrated pressure sensor, and hardware and software to run a user interface device screen that displays the device status, battery status, SEM Value, and SEM Delta ("SEM Δ"). The SEM Scanner (Model 200) is pre-calibrated. The SEM Scanner (Model 200) is provided with an inductive charging mat and power supply for recharging the device unit.

The SEM Scanner (Model 200) assesses changes in electrical capacitance of tissue and expresses the result in a SEM Value of 0.3 to 3.9. SEM is a unitless number (not an International System

of Unit). The SEM Scanner (Model 200) displays a Δ (delta) value after taking a minimum of three (3) SEM Values readings. A minimum of four readings were taken to obtain a result during the supporting clinical studies. The reported SEM Δ is used as an adjunct to the standard of care when assessing the heels and sacrum of patients who are at increased risk for pressure ulcers.

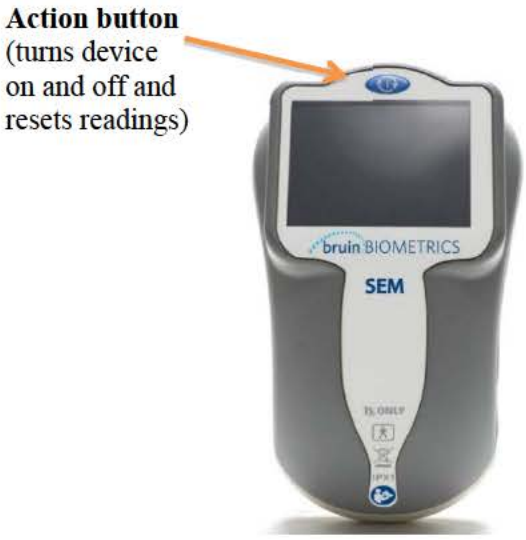

Figure 2. SEM Scanner (Model 200) Top View showing Display and Action Button

Figure 2. The electrode on the bottom of the SEM Scanner (Model 200)

Figure 3. SEM Scanner (Model 200) Side View

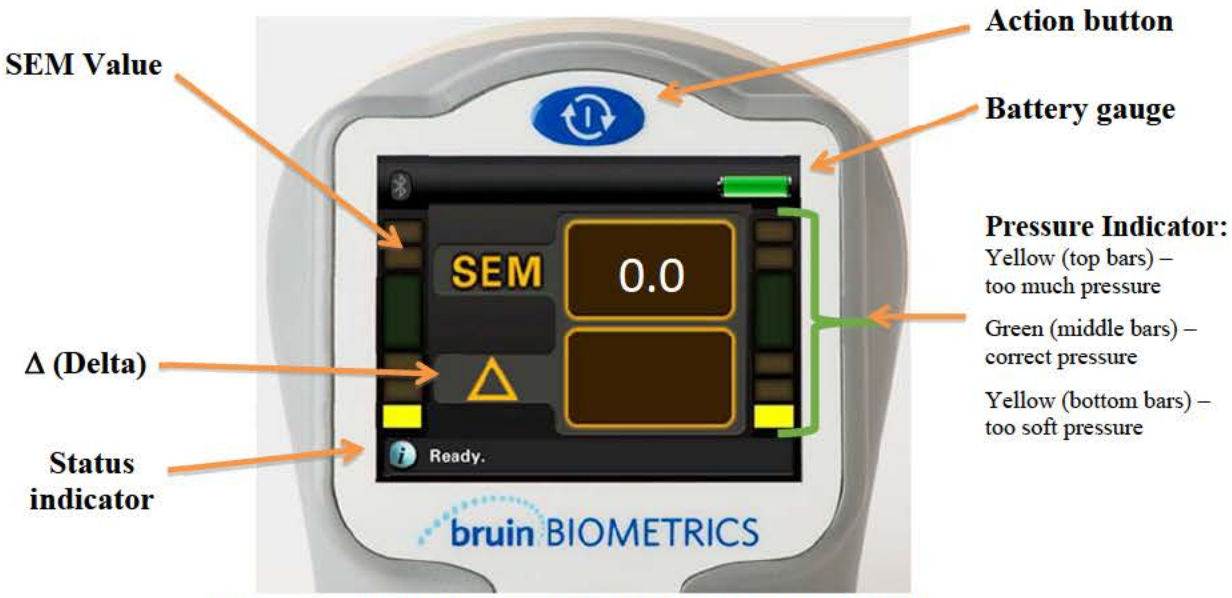

Figure 4. SEM Scanner (Model 200) Display (V3.60)

Item	Function
Action Button	Clears SEM readings and turns the Scanner unit ON/OFF.
Battery Gauge	Battery icon indicating current battery state of charge
Δ (Delta)	Calculated difference between the minimum and maximum SEM Values in the set of readings taken
SEM	Display of SEM Value for the last completed reading
Pressure Indicator	Bars indicating the applied pressure while taking a SEM reading. The color changes from yellow to green to yellow as applied pressure increases. Green bars indicate the correct pressure is applied to take the SEM reading and the SEM Value will show on the screen.
Status Indicator	Number of acquired readings, status indicator, or error messages

Table 1. Legend for Figure 4

A SEM Value of zero (0.0) shown on the display screen represents when the device is not measuring or when SEM readings are cleared out from the screen.

Product Specifications

Product Feature	Specification
Capacitance Range	(b) (4)

Product Feature	Specification
Method of Taking a Reading	Reading is triggered when pressure is applied to the electrodes
Battery Source	• Operates on a rechargeable lithium ion polymer batter • Continuous operation for at least 3 hours • Charges using inductively coupled energy transfer in a fully enclosed charging system • Includes a temperature detection component that will stop the battery from charging if the battery temperature threshold is exceeded
Device Unit Enclosure ("Packaging System")	• Integrated housing enclosure for the electrical components • No external connectors • No exposed electrically live element • IPX1 water ingress protection
Electrode System Package Support	Includes an elastomer support for the electrode
Environmental Requirements	Device operates over the range of 15 to 35°C at 5 to 90% humidity (non-condensing)

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS

The skin-contacting materials, such as the elastomer membrane, rubber, and polyimide materials, were tested to be biocompatible for the intended use of the device. Testing was conducted following FDA's guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"," issued June 16, 2016. Testing included:

- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity

The device did not cause an irritating, sensitizing or cytotoxic effect upon the skin.

SHELF LIFE/REPROCESSING

Cleaning and Disinfection Testing

The device is nonsterile. Cleaning and disinfection testing was conducted following FDA's guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," issued March 17, 2015.

Wear Testing – Repeat Exposure to Cleaning and Disinfection Agents

Wear testing was conducted to assess wear-induced failure of the device components and potential degradation of the seal material or functional performance due to exposure to cleaning agents used during cleaning and disinfection.

ELECTROMAGNETIC CAPABILITY & ELECTROMAGNETIC SAFETY

Electromagnetic Compatibility (EMC) and Electrical Safety verification testing were conducted to confirm the EMC and electrical safety of the device. Testing was conducted in accordance with:

- IEC 60601-1 (3rd edition), Medical Electrical Equipment – General Requirements for safety and essential performance
- EN 60601-1-2:2001/A1:2006, Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
- EN 60529-1:1992, Degrees of protection provided by enclosures (IP Code)

Test Description	Test Parameter
Electrostatic discharge	±6 contact discharge ± kV air discharge
Radiated, Radiofrequency, Electromagnetic Field Immunity	Radiated Immunity, 3 V/m, 80 – 2500 MHz, 80% AM at 1 kHz
Electrical Fast Transient/Burst	AC power ports, ±2 kV
Surge Immunity	AC power ports, ±1 and ±2 kV
Immunity to Conducted Disturbances, Induced by Radiofrequency Fields	AC power ports, 0.15-80 MHz, 3 V_{rms}, 80% AM at 1 kHz
Power Frequency Magnetic Field Immunity	3 A_{rms}/m
Voltage Dips and Short Interruption Immunity	AC power lines Reduction 30%, 25 periods Reduction 60%, 5 periods Reduction 100%, 0.5 periods Reduction 100%, (b) (4) periods

Test Description	Test Parameter
Radiated Emissions – CISPR 11	Class A
Conducted Emissions (AC Mains) – CISPR 11	Class A

Electrical safety testing per EN 60529-1 was also conducted to verify the degree of protection provided by the enclosure against access of persons to hazardous parts, water, and solid foreign objects.

MAGNETIC RESONANCE (MR) COMPATIBILITY

The SEM Scanner (Model 200) has not been tested for MR Compatibility and should not be used in an MRI suite.

SOFTWARE

The agency considers the software to be a minor level of concern (LOC) because inadvertent software errors (e.g., failures or latent design flaws) are unlikely to cause any injury to the patient or operator.

All of the elements of software information as outlined in FDA's guidance documents "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005) were provided.

Overall, the software documentation included in the De Novo request is in sufficient detail to provide reasonable assurance that the software will operate in a manner described in the specifications.

SUMMARY OF CLINICAL INFORMATION

A total of 12 study sites, nine US centers and three UK centers, participated in this prospective, multi-site, longitudinal, blinded study. In total, 77.8% of the enrolled subjects were from US centers and 22.2% were from UK centers. This study enrolled a total of 189 subjects, who had provided their written informed consent or by verbal/ written consent of the subjects' legally authorized representative, from April through November 2016.

The study was carried out by a clinical study team at each participating site comprised of a Principal Investigator, Study Coordinator, and individuals acting in study roles of "Generalists" and "Specialists." Daily assessments were limited to up to two assessors within each assessment team. Comprising one team, the role of the "Specialist" was assigned to nursing staff who were the facility's experts on wound care to continue "standard of care" evaluations. The "gold standard" in this case is the clinical judgment of the wound/tissue viability experts.

Comprising a second team, the role of the "Generalist" included individuals who did not provide pressure ulcer care to the enrolled subjects and consisted of a wider range of healthcare providers: wound experts, ward nurses, nursing assistants, or medical assistants.

Blinding between assessment teams, the Specialists and Generalists, was employed. The Study Coordinator acted as the "gate-keeper" to help maintain blinding. In addition to blinding between Specialists and Generalists, the study was also blinded to staff at BBI during enrollments by an independent consultant to BBI (PhD Epidemiologist) managing the Medrio database, an electronic data capture system. The purpose of this study was to compare the SEM Scanner to the current Standard of Care, Visual Skin Assessment (VSA), in identifying patients with tissue at increased risk of developing pressure ulcers at the heels or sacrum.

Enrolled subjects were expected to be evaluated once daily throughout the observation period for a minimum of 6 days to maximum of 21 days upon enrollment or until earlier exit from the study. The minimum of 6 days was selected to optimize the probability of observing an early pressure ulcer should one develop. The maximum of 21 days was selected to set expectations for the study sites on the upper bound for length of participation. The total number of evaluation days include the day of enrollment (day 0).

Daily assessments were performed at the sacrum and both heels unless the anatomical location(s) were not assessable. Daily assessments included:

- Specialist Risk Assessments
- Specialist Skin Assessment (including pressure ulcer diagnosis)
- Generalists SEM Scanner Readings
- Prevention/Intervention Questionnaire

Primary Endpoint:

Positive Detection is defined as observations of two or more SEM $\Delta > 0.5$ from three consecutive series of SEM Scanner readings prior to pressure ulcer diagnosis by clinical judgment of the Specialist. A sensitivity of at least 0.70 is defined for positive detection success as a measure of the primary effectiveness performance.

Negative Detection is defined as observations of two or more SEM $\Delta \leq 0.5$ from three consecutive series of SEM Scanner readings prior to no pressure ulcer diagnosis by clinical judgment of the Specialist. A specificity of at least 0.55 is defined for negative detection success as a measure of the primary effectiveness performance.

Safety Endpoint

For product safety, the measure of analysis was on the percentage of device-related adverse events reported in this study. A continued demonstration of no reports of device-related adverse events experienced by subjects and device users from direct use of the device is defined as a safety endpoint success.

Inclusion Criteria

1. Greater or equal to 55 years of age

2. At risk of developing a pressure ulcer at time of enrollment as defined by one or more of the following:
    a. PU Risk Score - Braden < 15; Waterlow ≥ 10; or Norton ≤ 18
    b. Poor mobility; e.g., Braden mobility subscore ≤ 2; Waterlow mobility subscore 2; Norton mobility subscore ≤ 2; or poor mobility according to clinical judgment (chair- or bed-bound)
    c. Poor nutrition; e.g., Braden nutrition subscore ≤ 2; Waterlow nutrition subscore 2; or poor nutrition according to clinical judgment
    d. Medical procedure (e.g. surgery, x-ray, etc.) involving immobility and inability to change position lasting 4 hours or longer
3. Evaluable by the study team for a minimum of 6 consecutive days upon enrollment
4. Willing and able to provide informed consent (or by proxy)

Exclusion Criteria

1. Unhealed (including newly diagnosed) pressure ulcer at any anatomical site at the time of enrollment
2. Broken skin at the sacrum and both heels that prevents collection of SEM Scanner readings from all three anatomical locations; possible assessment at only one or two locations is not grounds for exclusion
3. Moisture lesion or incontinence associated dermatitis at the sacrum
4. Physical, structural, or other limitations preventing assessments required in this study (e.g., suspected or actual injury preventing turning)
5. Presence of any condition(s) or injury(ies) which compromises the subject's ability to complete this study
6. Per clinical decision of the study Investigator, diminished decision-making capacity which might impact compliance or completion with study procedures
7. Patient modesty concerns on the part of the subject (or their proxy) that might impact collection of SEM Scanner readings at the anatomical location (heels and sacrum) to be assessed

Loss to Follow Up

No subjects withdrew from the study.

Protocol Deviations

There were no protocol deviations due to inclusion/exclusion criteria or withdrawal criteria.

At the West Coast site, there were 4 procedural protocol deviations related to missing SEM Scanner readings. The deviations regarding missing SEM Scanner readings occurred because obtaining the readings would have compromised subject safety, or the subject's concerns regarding modesty.

At the East Coast site, there were 34 procedural protocol deviations related to missing SEM Scanner readings and 27 procedural protocol deviations related to missing date of wound diagnosis. The deviations regarding missing SEM Scanner readings occurred because obtaining the readings would have compromised subject safety, or the subject's concerns regarding modesty. The deviations regarding date of wound diagnosis occurred because the nursing facility

where the study procedures took place often did not record the date of wound diagnosis in their records.

Specifically, 182 patients were listed as Intent to Treat (ITT). Of those, 170 Patients were included in the sensitivity and specificity calculations with 48 pressure ulcers forming across 36 Patients.

Within the 12 sites included in the study, the trials were completed in:

1. Orthopaedic Trauma: 14% (n=26 subjects)
2. Medical Surgery: 27% (n=50 subjects)
3. Long Term Care: 32% (n=58 subjects)
4. ICU: 9% (n=17 subjects)
5. Rehab: 4% (n=7 subjects)
6. Neurologic Care: 8% (n=15 subjects)
7. Other/Mixed: 5% (n=9 subjects)

Results – Primary Endpoint ITT

Of the 189 subjects, a total of 182 subjects with 437 anatomical locations were used to derive clinical validity of the SEM Scanner Δ values contributed to the intent-to-treat (ITT) data analysis performed per this study's Statistical Analysis Plan (SAP). **Table 1** reflects the distribution of pressure ulcers identified by VSA per Specialist' judgment that went into the ITT analysis.

Table 1. Pressure Ulcer (PU) Classification Included in ITT Analysis

	ITT (N = 182**)					
	All		Sacrum		Heels	
PU Classification, n = 48*	n	%	n	%	n	%
Stage I	32	66.7%	12	25%	20	41.7%
Stage II	3	6.3%	3	6.3%	0	0.0%
Stage III - IV	0	0.0%	0	0.0%	0	0.0%
Unstageable	2	4.2%	0	0.0%	2	4.2%
sDTI	11	22.9%	1	2.1%	10	20.8%

Source: Table 8b in SEM200-008 Final Study Report

Sacrum PUs w/insufficient SEM valid series for comparison: (b) (4), (b) (4) es (b) (4) and (b) (4) pressure ulcers because of non-analyzable data; not part of ITT

48 PUs developed in the Intent-to-Treat population (26% incidence in the ITT population) with a number of patients developing at least 1 PU at separate anatomical sites. Therefore the 48 PUs developed on 36 patients.

Table 2. Demographic Characteristics of Study Subjects

	ITT (N=182)	
Gender	n	(%)
Male	85	(46.70%)
Female	97	(53.30%)
Race		
White or Caucasian	121	(66.48%)
Black/ African American	8	(4.40%)
Asian	44	(24.18%)
American Indian/ Alaskan Native	1	(0.55%)
Pacific Islander/ Native Hawaiian	2	(1.10%)
Unknown	2	(1.10%)
Other	4	(2.20%)
Ethnicity		
Non-Hispanic/ Latino	158	(86.81%)
Hispanic/ Latino	8	(4.40%)
Unknown	12	(6.59%)
Does not wish to provide	4	(2.20%)
Fitzpatrick Skin type		
Type I (0-7)	60	(32.97%)
Type II (8-16)	67	(36.81%)
Type III (17-25)	43	(23.63%)
Type IV (26-30)	5	(2.75%)
Type V-VI (over 30)	4	(2.20%)
Missing	3	(1.65%)

Table Source: Table 2 in database of SEM200-008 Final Clinical Study Report

Sensitivity and specificity data presented in Tables 3a and 3b show how the SEM Scanner 200 compares to visual skin assessment in identifying patients with tissue at risk of developing pressure ulcers at the heels or sacrum.

In the 008 study, healthcare providers assessed 437 individual anatomical locations from 182 subjects in the ITT. These locations were classed as shown in Table 3a. Results from the 008 clinical study results from each assessed anatomy were classed as:

- True positives - a visible pressure ulcer and a localized SEM Δ of 0.6 or above ("abnormal levels of SEM"). Table 3a shows 42 anatomical sites in this category.

- True negatives - no visible pressure ulcer and a localized SEM Δ below 0.6 ("flat values"). Table 3a shows 128 anatomical sites in this category.

- False negatives - a visible pressure ulcer and a localized SEM Δ below 0.6 ("flat values"). Table 3a shows 6 anatomical sites in this category.

- False positives - no visible pressure ulcer and a localized SEM Δ of 0.6 or above ("abnormal levels of SEM"). Table 3a shows 261 anatomical sites in this category.

No subjects were enrolled in the study who were not at risk for developing PU. Performance of this device on subjects who are not at risk of developing PU was not conducted in this study nor considered in the sensitivity and specificity calculations.

Table 3a: Final results for individual anatomical locations for SEM Scanner from the 008 study

True Positive = 42	False Positive = 261	All positives 69%
False Negative = 6	True Negative = 128	All negatives 31%
	Total anatomical locations 437	Total patients in ITT population 182

In order to appropriately account for the within subject correlation in the estimates of the 95% confidence intervals for sensitivity and specificity, the bootstrap method used. The bootstrap method was applied by sampling, with replacement, from the original dataset. The sampling was done on a per subject basis such that all records for a randomly chosen subject were extracted. One thousand datasets were generated using this method, each with the same number of subjects as the original dataset.

Estimates of sensitivity and specificity were then calculated across datasets by taking the median value. The confidence limits were generated from the 2.5th and 97.5th percentiles. This resulted in the following estimates (Table 3b).

Table 3b. Range of SEM Δ and Confidence Intervals Using Bootstrap Method

	Sensitivity[1]			**Specificity[1]**		
SEM Δ	n	%	95% CI	n	%	95% CI
>0.5	42	87.4%	77.8%, 96.7%	124	33.0%	27.6%, 38.7%

[1]. Sensitivity and specificity analysis was performed following an analysis rule of 2 of 3 consecutive observations of a SEM **Δ** of 0.6 or above ("SEM positive") or SEM **Δ** of 0.5 or less ("SEM negative") from a five-day window from study exit or when a pressure ulcer is identified by visual skin assessment. This analysis rule was defined before study analysis was performed.

The study was successful in meeting the sensitivity endpoint of at least 70% for positive detection success. ITT study results demonstrated a sensitivity of (b) (4)% (95% CI: (b) (4)% - (b) (4)%) for detecting pressure ulcers between the SEM Scanner and clinical judgment per visual skin assessment.

The ITT study results showed a specificity of (b) (4)% (95% CI (b) (4)% - (b) (4)%) in this study. This did not meet the specificity endpoint of at least 55% for negative detection success.

Safety Endpoint Results
Of the 189 patients enrolled in this study, there were zero (0%) reports of adverse events related to use of the SEM Scanner device units, which meets the safety endpoint of the study. In total, adverse events from five subjects were reported in this study. Four of the five events were categorized as unrelated, and the remaining one event was because of underlying disease.

Interpretation of the Δ Symbol:

- A $\Delta \leq 0.6$ (0.5 and below) at an anatomical site may suggest the tissue is not at increased risk for pressure ulcers
- A $\Delta > 0.6$ (0.6 and above) at an anatomical site may suggest increased risk for pressure ulcers ("positive")

The Δ value should be considered in conjunction with other measures of standard of care and clinical judgment.

Pediatric Extrapolation

In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

LABELING

Labeling meets the requirements for prescription use in accordance with 21 CFR § 801.109. Labeling for the device includes the following:

- Instructions on how to operate the device with explanations of user-interface features.
- Instructions to clean and disinfect the device between each patient.
- A contraindication that the device is not to be used on open wounds, in order to reduce the potential for cross-contamination between patients.
- A statement indicating that the device is not intended to be used as a standalone device, but rather as an adjunct to clinical judgment. Any decision to intervene or not should be based solely on the experience and expertise of the clinician.
- Information on electrical safety and electromagnetic compatibility.

RISKS TO HEALTH

The risks associated with the pressure ulcer management tool are adverse tissue reaction, transmission of infection between patients, electromagnetic interference with patient monitoring equipment, and electrical shock. The severity and incidence of these risks to health are relatively low due to the very limited patient contact with the device. As such, general controls are sufficient to mitigate these risks and reasonably assure safety and effectiveness. General controls include but are not limited to good manufacturing practice requirements (21 CFR part 820), including design controls (820.30) due to the inclusion of software, and general labeling (21 CFR part 801).

BENEFIT-RISK DETERMINATION

The SEM Scanner Model 200 is a hand-held, portable device that consists of a single electrode sensor, an integrated pressure sensor, and hardware and software to run a user interface device screen. The risks to health associated with SEM Scanner Model 200 include adverse tissue reaction, transmission of infection between patients, electromagnetic interference with patient monitoring equipment, and electrical shock, none of which occurred in the clinical trial. These risks are considered low and can be mitigated with general controls.

The performance characteristics of this device reveals a sensitivity of 87% and a specificity of 33% in a population at risk for pressure ulcers. These outcomes demonstrate a clinical benefit as an adjunct to standard of care to help identify patients at increased risk for pressure ulcer where further interventions can be beneficial. As stated in the warnings in the labeling, readings from the device should never be used to support reduced intervention compared to standard of care

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

> The SEM Scanner (Model 200) is intended to be used by healthcare professionals as an adjunct to standard of care when assessing the heels and sacrum of patients who are at increased risk for pressure ulcers.

The probable benefits outweigh the probable risks for the SEM Scanner (Model 200). The device provides benefits and the risks can be mitigated by the use of general controls.

CONCLUSION

The De Novo request for the SEM Scanner (Model 200) is granted and the device is classified as follows:

Product Code: QEF
Device Type: Pressure ulcer management tool
Class: I (Exempt from premarket notification review, subject to limitations in 21 CFR 876.9)
Regulation Number: 21 CFR 876.2100