WoundVision 510(k) SUMMARY

1. Submitted by:	WoundVision LLC 5410 Emerson Way, Suite 1 Indianapolis, IN 46226
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Date of Summary Preparation:	December 6th, 2013
2. Names:	***Proprietary Name:*** WoundVision Scout
	Common Name: Scout
	Device Classification: 21 CFR 878.4160 Regulation Name: Surgical camera and accessories Regulatory Class: Class I Product Code: FXN
3. Marketed Device(s) to Which Equivalency is Claimed:	Aranz Medical, Silhouette, K070426
4. Device Description:	The **Scout** is a combination digital camera and long-wave infrared camera. The clinician simultaneously captures a visual and infrared image that can be uploaded and stored with a patient's electronic medical record. Body surface size and thermal intensity data can be measured and recorded. The digital camera captures the visible light wavelengths from the electromagnetic spectrum that is visible to the human eye. The infrared camera captures the infrared radiation emitted by the human body from the electromagnetic spectrum that is not visible to the human eye. Both cameras are housed in a plastic casing which transmits captured data to a PC.

5. Intended Use:	The Scout is a combination digital camera and long-wave infrared camera. The digital camera is indicated for the use of capturing visual images to measure the diameter, surface area, and perimeter of a part of the body or two body surfaces. The long-wave infrared camera is indicated for the use of capturing thermal images to measure the thermal intensity data of a part of the body or two body surfaces. Both components of the Scout are non-contact with respect to the patient and provide an adjunctive tool to help a trained and qualified health care professional measure and record external wound and body surface data. Intended for qualified healthcare professionals who are trained in its use, the Scout is a non-invasive and non-radiating device. The Scout is to be used on a patient population that includes non-pregnant female or male patients 18 years of age or older. The Scout is intended to be used in hospital, acute and sub-acute care settings, long term care, surgery, health care practitioner facilities, outpatient, home healthcare, or in any environment where health care is provided by a qualified health care professional. The Scout does not provide a diagnosis or therapy. **Discussion of Intended Use Differences:** Although the intended use of WoundVision Scout differs from that of the predicate, none of the differences are critical to the use of the device nor do they affect the safety and effectiveness of the device. The Scout is able to use a visual image to obtain standard wound measurements similar to the predicate. By using a technology that combines a substantially equivalent method for measuring visual images with a method for measuring thermal images, the Scout also allows for a physiological measurement of thermal intensity data of a part of the body or two body surfaces adjunctive to the visual camera. The Scout's long-wave infrared camera and features serve as an auxiliary component and secondary measure (adjunct) to the Scout's substantially equivalent visual camera. Bench testing and clinical usability testing indicates that the method for obtaining relative thermal intensity data of the anatomical measurement site is reliable and repeatable.	
6. Predicate Device Technology Comparison Chart:	**Scout**	**Silhouette**
Similarities		
Measurement	*Measure the diameter, surface area, and perimeter of a part of the body or the distance between two body surfaces.*	*Wound measurement and documentation on all external wound types.*

Life Supporting/Sustaining	*Non-life supporting/sustaining*	*Non-life supporting/sustaining*
Implant	*Not an implant*	*Not an implant*
Category	*Pre-market Notification 510(k)*	*Exempt*
Differences		
Technology	*Electronically records & stores source data (images & measurements).*	*Electronically records & stores source data (images & measurements).*
Method	*Non-patient contacting*	*Non-patient contacting*
	Powered	*Powered*
Material	*Molded plastic*	*Molded plastic*
Measurement	*Measures the diameter, perimeter and surface area of a part of the body or two body surfaces using a visual image & measures the thermal intensity variation data of a part of the body or two body surfaces using a thermal image.*	*Wound measurement and documentation on all external wound types.*
	Discussion of Technological Differences: The two main differences between the Scout and its predicate device is that the Scout combines measurement of size with the measurement of thermal intensity. The differences in technology of the Scout and its predicate do not affect safety and effectiveness.	

Clinical Testing:	
	I. **Accuracy and Reproducibility of the Scout [WV13CL-0004]** ***Objectives and Purpose:*** Nineteen metal shapes with known areas were imaged, each with 3 pre-defined head directions to simulate 57 different wounds. The area of each object was calculated in cm^2 utilizing three different methodologies: • the reference standard LxW (diameter) ruler method as recommended in the NPUAP PUSH Tool v 3.0 ("Ruler LxW Area") • the Scout LxW ("Scout LxW Area") • the Scout Trace ("Scout Trace Area" and "Scout Perimeter") Each shape was measured by three clinicians twice, using each of the three measurement methodologies (six measurements for each shape's predefined head direction). The Coefficient of Individual Agreement (CIA) methodology was utilized to compare the clinical reference standard ruler LxW area, the Scout LxW area, and the Scout Trace methodology. The accuracy of the area calculated by each of the three methods (ruler LxW, Scout LxW, and the Scout Trace) was determined by comparing results to the known area of metal objects produced by a calibrated CNC Mill (Haas Model VF3) with Mastercam X6 machining software. Both inter- and intra-rater reliability of each measurement were assessed.

Results:

- The determination of area utilizing the Scout LxW function was equivalent with the clinical reference standard ruler LxW (Psi_R =.77, 95% CI (0.53, 1.02).
- Both the ruler LxW and the Scout LxW measurements overestimate the true area by approximately 37-40%.
- The Scout Trace was the most accurate measure and resulted in area approximately 4% different than the true area and 2% different than the true perimeter.
- While the within-operator precision is better, the within and between operator precision is acceptable for all measurements (median %CV < 5) with the Scout Perimeter being the least variable.

The within operator precision:

- Scout Perimeter 1.94 CV%
- Scout Trace Area 2.54 CV%
- Scout LxW Area 3.87 CV%

The between operator precision:

- Scout Perimeter 1.97 CV%
- Scout Trace Area 2.80 CV%
- Scout LxW Area 4.20 CV%

In conclusion, the Scout LxW method is equivalent to the current clinical reference standard ruler LxW for calculating area. The Scout Trace method results in an area much closer to the true area than either the ruler LxW or the Scout LxW method. The within and between operator precision median %CV is less than 5 for all measurements.

II. **Comparison of Standardized Clinical Evaluation of Wounds Using Ruler Length by Width and Scout Length by Width Measure and Scout Perimeter Trace [WV13CL-0006]**

Objectives and Purpose: Performance of the Scout device and data was evaluated for 40 wound images that were captured in clinical outpatient and inpatient settings. Each of the 40 wound images were measured 3 times by 5 independent operators using the Scout. Analyses were completed to demonstrate the coefficient of variation for within and between operator for Scout LxW Area and Trace Area and Perimeter measurements.

The results of this study demonstrate:

- The within operator precision is acceptable (median CV% <10) for all three measurements.
  - Scout Perimeter 2.35 CV%
  - Scout Trace Area 3.72 CV%
  - Scout LxW Area 6.26 CV%

- The between operator variability is larger than the within but is still <10% for all measurements (median %CV). The larger variability between readers suggests the differences in subjective perception of qualitative wound characteristics (wound edge) may influence wound assessment agreement and thus is to be expected.
    - Scout Perimeter 3.71 CV%
    - Scout Trace Area 9.29 CV%
    - Scout LxW Area 9.82 CV%
- *The within operator results with actual wounds, median CV% 2.35-6.26, are similar to those on simulated wounds of known size, median CV% 1.94-3.87 (WV13CL-0004)* demonstrating that the device gives reliable results when used in the clinical setting for repeat measurements by the same operator.
- The between operator results with actual wounds median CV% 3.71-9.82, are greater than those on simulated wounds of known size, median CV% 1.97-4.20. The determination of the shape or wound edge is cleaner with metal objects than with an actual wound image. These results are in alignment with findings reported in the literature that show the between operator differences exist not because of the measurement technique but instead due to the judgment of the operator performing the measurement. However, the between operator median %CV is less than 10 for all methodologies.
- Scout can be used by operators with varied backgrounds and provides similar results when clinical experts and non-clinicians utilize the device.
- Scout has been shown to provide reliable wound measurements on patient wounds captured in a clinical setting.
- Scout provides accurate and reliable measurements of wound size, with the Scout Perimeter being the least variable.

Summary:

- The data from this study suggests that a single operator can measure the same wound multiple times similarly. And as expected, multiple operators do not measure the same wound as well as a single operator. The variation that exists between readers in wound measurement is not necessarily due to the measurement technique but instead the judgment of the operator in determining the wound edges performing the measurement.
- The within and between operator precision is acceptable for all measures but is similar for the Scout Trace Area (median %CV within- 3.72 and between 9.29) and the Scout LxW (median %CV within 6.26 and between 9.82). Perimeter measurement is more precise than both Traced Area and Scout LxW (median %CV within 2.35 and between 3.71). For all measurements, the within operator precision is better than the between operator.

- The results in the table below are similar to those observed in the study using simulated wounds of known size demonstrating that the Scout device provided acceptable results when utilized on patient wounds.

Measurement Technique	Within Shape Median CV%	Within Wound Median CV%	Between Median CV%	Between Wound Median CV%
Scout LxW	3.87	6.26	4.20	9.82
Scout Trace Area	2.54	3.72	2.80	9.29
Scout Trace Perimeter	1.94	2.35	1.97	3.71

Bench Testing:

I. Accuracy of Thermal Image Data at Varied Camera Angles [WV13REP-0005]

Objectives and Purpose: To show that the thermal image data (thermal pixel values) acquired is consistent when the angle of the imager to a calibrated target changes. The target captured in each image using the Scout and ImageCapture will be analyzed using Scout ImageReview to measure outcome of the endpoints. It is expected that there may be some variation in the thermal pixel values measured but that when there are variances, it will be a simple shift of the measured endpoints with a variance under +/- 6 pixels of the target temperature.

Results: The hypothesis was confirmed with this test. There was some variation in the thermal pixel values measured but the variance was a small shift of the measured endpoints with a variance under +/- 6 pixels of the target temperature.

II. Trend of Thermal Image Data Utilizing Scout [WV13REP-0006]

Objectives and Purpose: The target captured in each image using Scout will be analyzed using Scout ImageReview software to measure the outcome of the endpoints over time. It is expected that there may be some variation in the thermal pixel values measured of the target but that the variation pattern should be similar amongst all imagers tested regardless of target temperature.

Results: Variation in the thermal pixel values measured on the target were discovered. The variation pattern was similar amongst all imagers tested regardless of target temperature. All three imager's at all three temperatures trended downward in thermal pixel value for the first 15-20 minutes after imager power on and then thermal pixel value started to trend upward.

III. Validation of the Thermal Intensity Scale Using a Scout Imager [WV13REP-0007]

Objectives and Purpose: To determine the accuracy of the scale of approximately 12.7 pixels per 1°C. 12.7 pixels is determined from a 20°C range across a 254 pixel value range (254/20 = 12.7 pixels per 1C). The L3 thermal camera core

contains 254 unique pixel values evenly distributed across approximately 20°C and it expected that the difference in pixel value between each degree C will be 12.7 (+/- 2 pixels) throughout the temperature range.

Results: The hypothesis was confirmed with this test. The difference in pixel value between each degree C was 12.7 (+/- 2 pixels) throughout the temperature range.

IV. Determining Distance Impact on Thermal Intensity Utilizing Scout Imager [WV13REP-0008]

Objectives and Purpose: To determine how distance affects the thermal intensity of a calibrated, unchanging target. It is expected that thermal intensity will vary based on the distance of image capture. The variation will be no greater than a +/- 6 mean pixel value per 6" of distance change.

Results: The hypothesis was confirmed with this test. The thermal variation was not greater than a +/- 6 mode pixel value per 6" of distance change. Further, the largest variation recorded during the test was +3 pixel values.

V. Determining Environment Temperature Impact on Thermal Intensity Utilizing a Scout Imager [WV13REP-0009]

Objectives and Purpose: To determine how environmental temperature affects the thermal intensity of a calibrated, unchanging target. Thermal intensity pixel value is affected by environmental temperature when the image was captured.

Results: The hypothesis was confirmed that environmental temperature does affect the thermal pixel value displayed by the thermal imager. The amount of the effect could not be conclusively confirmed from the data collected. The outcome of this test confirms need for the use of relative pixel value.

VI. Determining FOV Correction Impact on Thermal Intensity [WV13REP-0010]

Objectives and Purpose: To determine how the applied thermal image field of view (FOV) correction affects thermal intensity.

Results: Thermal intensity pixel value is not affected by the applied FOV correction to the thermal image. Across 30 data comparison points, only two displayed a slight mode difference of 1 pixel value.

VII. Determining the Size Correction Accuracy Applied to the Thermal Image [WV13REP-0011]

Objectives and Purpose: To determine how equivalent the thermal image is to the unaltered visual image after a scale correction is applied to the thermal.

Results: The average % change between the Visual Image and Thermal Image

	after correction was -3.29%. The average % change between the Visual Image and the Thermal Image without correction was 15.58%.
Conclusions:	
	In conclusion, clinical and non-clinical data supports the substantial equivalence of the Scout visual camera and measurements to its predicate and proves those measurements to be repeatable and reliable. The tests also support the validation and accuracy of the adjunctive long-wave infrared camera.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2013

WoundVision, LLC
c/o Pearl Pathways
Gretchen Miller Bowker
29 East McCarty Street, Suite 100
Indianapolis, Indiana 46225

Re: K131596
Trade/Device Name: WoundVision Scout
Regulation Number: 21 CFR 878.4160
Regulation Name: Surgical camera and accessories
Regulatory Class: Class I
Product Code: FXN
Dated: October 30, 2013
Received: October 31, 2013

Dear Ms. Bowker:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WOUNDVISION

INDICATIONS FOR USE

510(k) Number (if known): K131596
Device Name: Scout

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Intended for qualified healthcare professionals who are trained in its use, the Scout is a non-invasive and non-radiating device.

The Scout is to be used on a patient population that includes non-pregnant female or male patients 18 years of age or older. The Scout is intended to be used in hospital, acute and sub-acute care settings, long term care, surgery, health care practitioner facilities, outpatient, home healthcare, or in any environment where health care is provided by a qualified health care professional.

The Scout does not provide a diagnosis or therapy.

Prescription Use __X__ **AND/OR** **Over-the-Counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
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(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K131596