August 9, 2018

CHRISTIE MEDICAL HOLDINGS, Inc.
% Diane Horwitz
Regulatory Consultant
Mandell Horwitz Consultants LLC
2995 Steven Martin Drive
Fairfax, Virginia 20031

Re: K171245
Trade/Device Name: Presygen™/si-1
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: July 11, 2018
Received: July 12, 2018

Dear Diane Horwitz:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171245

Device Name
Presygen™/si-1

Indications for Use *(Describe)*
Presygen™/si-1 is indicated for use in hospital facilities, along with clinical assessment of signs and symptoms, by healthcare professionals for non-invasive and non-diagnostic measure of relative temporal variation in oxygen saturation (StO2) in superficial tissue. Presygen™/si-1 displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports tissue oxygenation measurements in selected tissue regions. Presygen™/si-1 is intended for adults only (22 and over).

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

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

CHRISTIE MEDICAL HOLDINGS, INC.
3175 Lenox Park Boulevard, Suite 200
Memphis, TN 38115

1.2 Official Correspondent

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1.3 Date of Preparation

August 9, 2018

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name, 510(k) Number

Presygen™/si-1, K171245

2.1.2 Common/Usual Name

Tissue Saturation Oximeter

2.1.3 Classification Information

Classification Name:	Oximeter
Classification Regulation:	21 CFR 870.2700
Class:	2
Product Code:	MUD
Panel:	Cardiovascular

3. PREDICATE DEVICE AND REFERENCE DEVICE

The predicate device is Kent Camera (Kent Imaging, Inc., K113507). The reference device is T.Ox™ (Vioptix, Inc., K042657).

4. DESCRIPTION OF THE DEVICE

Presygen™/si-1 is a standalone, non-contact tissue oxygen saturation oximeter based on multispectral optical imaging techniques. The mode of action is to transmit lights at four (4) known

wavelengths through blood in superficial tissue and measure the tissue oxygen saturation (StO_2), based on the amount of diffusely reflected light.

The Presygen™/si-1 software provides user control of the device and access to stored data, through a Graphical User Interface (GUI). The software controls various hardware elements of the device such as illuminators, sensors, display and Input/Output, and manages communication between these elements and between processors and memory. The software also performs calculations to derive Tissue Oxygen Saturation (StO_2) from optical inputs and display this to the device user in a two-dimension (2D) spatial map.

The Presygen™/si-1 device has been designed with the additional capability of compensating for melanin levels in the skin, since absorption of light by melanin affects the measurement of the oxygenated hemoglobin and deoxygenated hemoglobin through the skin.

The device consists of the following:

- Imaging head: Contains optics, lasers, and electronics to display the $\%StO_2$
- Base compartment: Includes the wheels, brakes mechanism, SMB (Smart Multi-Media Board), power switch, certified power supply, fans, filters and cabling
- Touchscreen monitor display: User interface, display of image, and patient data
- Keyboard: Used to enter user or patient information into the device
- Accessory: The Presygen™/si-1 Sterilized Drape is a prepackaged single-use third party drape that is used with Presygen™/si-1 to avoid contamination during the imaging process.

5. INDICATIONS FOR USE

The indication for use statement for Presygen™/si-1 is shown below.

Presygen™/si-1 is indicated for use in hospital facilities, along with clinical assessment of signs and symptoms, by healthcare professionals for non-invasive and non-diagnostic measure of relative temporal variation in oxygen saturation (StO2) in superficial tissue. Presygen™/si-1 displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports tissue oxygenation measurements in selected tissue regions. Presygen™/si-1 is intended for adults only (22 and over).

6. INDICATIONS FOR USE COMPARED TO THE PREDICATE

The indications for use statement for Presygen™/si-1 system is similar to the predicate device. The devices share the same target patient population, the same users and conditions of use. Both devices are Rx-only.

Table 1. Indications for Use Comparison for Presygen™/si-1 Versus the Predicate

Subject Device **Presygen™/si-1** **(Christie Medical Holdings, Inc.)**	**Predicate: K113507** **Kent Camera** **(Kent Imaging Inc.)**
Presygen™/si-1 is indicated for use in hospital facilities, along with clinical assessment of signs and symptoms, by healthcare professionals for non-invasive and non-diagnostic measure of relative temporal variation in oxygen saturation (StO2) in	The Kent Camera is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of: • oxygen saturation (StO2j,

Subject Device Presygen™/si-1 (Christie Medical Holdings, Inc.)	Predicate: K113507 Kent Camera (Kent Imaging Inc.)
superficial tissue. Presygen™/si-1 displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports tissue oxygenation measurements in selected tissue regions. Presygen™/si-1 is intended for adults only (22 and over).	• oxyhemoglobin level (HbO2), and • deoxyhemoglobin (Hb) level in superficial tissue. The Kent Camera displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports multispectral tissue oxygenation measurements for selected tissue regions. The Kent Camera is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

A comparison of the technological features between Presygen™/si-1 device and the predicate is shown in **Table 1** below.

Table 2. Technology Comparison for Presygen™/si-1 Versus the Predicate

Technological Characteristic	Subject Device Presygen™/si-1 (Christie Medical Holdings, Inc.)	Predicate: K113507 Kent Camera (Kent Imaging Inc.)
Measured Parameters	• StO_2	• StO_2 • HbO_2 • Hb
Operating principle	Spectral Analysis at specific wavelengths of light returned from target tissue.	Same
Patient Contact	Sensors in imaging head do not touch patient skin.	Same
Output Display	Two-dimensional color-coded map (image) of relative % oxygen saturation (%StO_2). Numeric data output available.	Same
Light Energy Delivered	Multiple wavelengths of Near-infrared light (NIR) Source: Light emitting diodes (LEDs)	Same
Energy delivered	Wavelengths: 740, 780, 850, 945 nm Visible lasers for properly focusing device (wavelength 515 nm)	Wavelengths: 670, 735, 890, 940 nm Visible lasers for properly focusing device (wavelength details not available)
Power source	Mains powered Rating: 100-240 Vac, 50-60Hz, 198 VA	Mains powered Rating: 90-240 Vac, 50-60Hz, 150 Watts
Output to user	Color-coded %StO_2 map. User capture images for future reference.	Same

Technological Characteristic	Subject Device Presygen™/si-1 (Christie Medical Holdings, Inc.)	Predicate: K113507 Kent Camera (Kent Imaging Inc.)
Monitor view	Immediate live view of the image during a surgical procedure using the touch-screen monitor	No immediate view of the image during an operation in the touch-screen monitor
SMC (Small Motion Correction) module in the software	Presygen™/si-1 system uses SMC (Small Motion Correction) to track ROI (regions of interest) using spatial registration to compensate for up to 23 x 23 mm translation (X and Y axis) for small motions of the imaging head or subject (e.g., during breathing)	Feature not available. Kent camera acts as a still-image camera.
Melanin Calibration	Prior to each session, a melanin calibration is performed for planned imaging areas in the subject to compensate for skin melanin levels in tissue	No calibration for melanin is performed. Note that the ViOptix ODISsey Tissue Oximeter (K042657) is a 510(k)-cleared device with measurements that are independent of melanin concentration. This device is considered a Reference Device.
ROI Plot	"Region of Interest" Plot: The user has the option of both saving and displaying StO_2 levels from user-selected regions of interest over a maximum of 5 minutes in the form of a line graph	Feature not available
Presygen™/si-1 Sterilized Drape Accessory	Yes. A sterile single-use drape is obtained sterilized and pre-packaged from a third-party vendor and is used during imaging.	Kent Camera does not have a sterile drape

7.1 Similarities and Differences in Technology Comparison

The fundamental technology of the Presygen™/si-1 device is the same as the predicate device: The measured parameters, operating principle, patient contact, output display, materials, light energy delivered, power source and output to user are all the same. The energy delivered (NIR and Visible wavelengths) are similar.

It is acknowledged that there are also some differences: the subject device has features such as live view of images on the monitor, a calibration method to aid in the imaging of different skin tones, a correction for small motion changes of the test location. The subject device includes a sterile single-use drape accessory to cover the optical head and arm. Despite the differences between Presygen™/si-1 and the predicate, extensive bench testing, software verification and validation, usability testing and two comparative clinical performance studies were conducted under design controls to demonstrate that the Presygen™/si-1 device meets its design specifications and that the differences from the predicate do not adversely impact safety or effectiveness.

8. PERFORMANCE TESTING

The 510(k) submission provided performance data to establish the substantial equivalence of the Presygen™/si-1 to the predicate device. A summary of these performance tests is provided below.

Sterilization, Storage, and Packaging: Presygen™/si-1 is a non-sterile imaging device and it is used with the Presygen™/si-1 Sterilized Drape as a pre-packaged single-use accessory from a Third-Party. Verification and validation testing for usage with Presygen™/si-1 together with the Presygen™/si-1 sterile drape met all acceptance criteria. In addition, the sterile drape was used successfully in the usability studies and in the clinical study that support this application.

Presygen™/si-1 device storage has been validated successfully under the proposed storage conditions of -9° to +140° F (-23° to 60°C), and operating conditions of 60° to 86°F (16° to 30°C), which is standard for many electronic medical device products.

Transportation, handling, and packaging strength were tested according to the applicable sections of ASTM D4169-16 by a third party and met the acceptance criteria.

Software Verification and Validation Testing: Software verification and validation testing was conducted according applicable sections of IEC 62304-06 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." The software for this device was considered as a "moderate" level of concern. Unit- and system-level software verification and validation testing demonstrated that the system performs as intended. The software successfully passed all requirements.

Electrical and Electromagnetic Compatibility: The Presygen™/si-1 was tested to international electrical and electromagnetic safety testing in accordance with AAMI ANSI ES 60601-1-12 and IEC 60601-1-2-07., and the device met the standards.

Bench (Performance) Testing: Christie Medical Holdings, Inc. performed a series of bench tests to demonstrate that Presygen™/si-1 meets its performance specifications; the device passed all test requirements and met the acceptance criteria for performance. The Bench Performance Tests were as follows:

- Mechanical component tests
- Vibration, temperature, and humidity specific conditions tests
- Presygen™/si-1 sterile drape usage functionality device test
- Cleaning agents and cleaning process in health care setting tests
- Electrical sensors functionality tests
- Electrical circuit boards functionality tests
- Optical functionality tests
- Phantom study

Optical Safety: The system belongs in the Low Risk Group according to IEC 62471-06, Photobiological safety of lamps and lamp systems.

Laser Safety: The system is a laser product of Class 1 according to 21 CFR §1040.10 and complies with IEC 60825-07.

Usability Testing: Presygen™/si-1 performed as intended according to AAMI ANSI IEC 62366-1-15, Application of usability engineering to medical devices.

Phantom Testing:
Study Objectives:
An independent bench validation phantom study was conducted to evaluate measurement accuracy and spatial uniformity of StO_2 values as a secondary validation for (StO_2% measurement range of 50%-90%) in which 3 phantom sets were generated with varying %StO_2 at high, medium and low levels (target levels of 90%, 70% and 50% StO_2, respectively). These phantoms were fabricated using a mixture of human hemoglobin tuned to the target StO2 value and polystyrene microspheres, which act as optical scatterers similar to human tissue. The spectrophotometer measurements for the controlled samples, vs. the measurements of Presygen™/si-1 %StO_2 were statistically evaluated to demonstrate the Presygen™/si-1 measurement accuracy in %StO_2 and the spatial variations across the imaging field.

Results:
The results of this testing demonstrated a significant linear trend of %StO_2 in a plot of actual vs. theoretical values using a target confidence of 95%. Phantom results indicate that the results are acceptably uniform over the device field of view.

Clinical Studies: A series of two studies were conducted comparing tissue oxygen saturation (StO_2) measurements taken with Presygen™/si-1 system versus the Kent Camera [K113507] and with Presygen™/si-1 system and the T.Ox™ Tissue Oximeter [K042657]. The study objectives were:

- To provide clinical evidence to support the claim that Presygen™/si-1 is substantially equivalent to Kent Camera, with a particular focus on subjects in Fitzpatrick Skin Type Scale I and II.
- To compare the measurement of StO_2 between Presygen™/si-1 and T.Ox™ Tissue Oximeter in subjects across Fitzpatrick Skin Type Scales I through V since the device output is not significantly affected by melanin.

Clinical Study 1
Clinical Study 1 Objectives:
Study number 1 was a prospective, unblinded, convenience sample population volunteers from the general community (no health information collected) for 55 subjects (199 data points) from ages 22 years and older, male and female. Fifty-two subjects (10 male and 42 female) were included in data analysis and three subjects were excluded due to incomplete data associated with device issues. To evaluate the effect of patient skin type, subjects were stratified across five (5) Fitzpatrick Skin Type Scales. Subjects had static images taken of target areas [on the thenar eminence and ventral forearm] with all three devices.

Clinical Study 1 Results:
A Vascular Occlusion Test (VOT) was conducted with all devices to evaluate performance during ischemia and reperfusion over a clinically meaningful dynamic range of StO2. The %StO2 results measurement range was 40% to 90%.

Presygen™/si-1 compared to the Kent camera in Fitzpatrick Scale I with >95% of the observations within the Limits of Agreement on the Bland-Altman with repeated measures and Deming Regression with bootstrap resampling results showing a slope with 95% confidence limits

including 1. The intercept for the Deming regression equation did not contain 0, however, demonstrating a small positive bias in the measurement of StO_2. The assessment of precision found the coefficient of variation was within 2 standard deviations of the mean for >95% of all observations in the measurement of StO_2 in Fitzpatrick I and II. Presygen™/si-1, Kent Camera, and T.Ox™ all demonstrate similar reactions to ischemia and reperfusion in the measurement of StO_2.

Clinical Study 1 VOT Results:
VOT data for Presygen™/si-1, Kent Camera, and T.Ox™ Tissue Oximeter all demonstrate similar reactions to ischemia and reperfusion in the measurement of $\%StO_2$. The VOT graphs for all three devices show similar patterns of baseline, response to ischemia and reperfusion. Data from the vascular occlusion test shows $\%StO_2$ stable at baseline, decreasing through ischemia and rebounding during reperfusion for both Presygen™/si-1 and Kent Camera, and between Presygen™/si-1 and T.Ox™ Tissue Oximeter.

Clinical Study 1 VOT Re-analysis:
Reanalysis of Clinical Study 1 VOT data was conducted to evaluate the measured temporal StO2 change between Presygen™/si-1 and the reference device (T.Ox™). The measured temporal StO2 change (ΔStO2) was calculated as the measured StO2 value subtracted by the mean StO2 value of the entire time series for a specific subject. The Bland-Altman plot showed most of the data is centered close to a Mean Bias that is close to 0; 91% of the observations are within the Limits of Agreement. It should be noted that the paired VOT measurements were collected on two different arms and at separate time intervals which generates an additional source of variation. Bland-Altman analysis showed a mean difference of 0.110 %StO2 with Limits of Agreement (-9.052, 9.273). The analysis of the correlation between the ΔStO2 by Deming regression shows equivalence to T.Ox™ with intercepts that are close to 0 and slopes that are close to 1. Deming Regression Analysis showed an intercept of 0.00 %StO2 with a 95% CI (-0.282, 0.278) and a slope of 0.773 with a 95% CI (0.708, 0.845). The histogram plot demonstrates that the differences in the ΔStO2 are distributed evenly around 0.

Throughout the study there was no SAE (Serious Adverse Events) or AE (Adverse Events) observed.

Clinical Study 2
Clinical Study 2 Objectives:
Study number 2 was also a prospective, unblinded, convenience sample population who self-reported as being healthy for 20 subjects (6 male, 14 female) from ages 22 years and older, male and female in a laboratory setting. The aim of this study was to provide data to compare StO_2 values in the left and right forearm using Presygen™/si-1 (subject device), Kent Camera (predicate device; Fitzpatrick Scales I and II) and T.Ox™ (reference device; Fitzpatrick Skin Type Scales I through V). Test conditions included static measurements and VOT.

Primary effectiveness included evaluation with the predicate device (Kent Camera) and reference device (T.Ox™ Tissue Oximeter) using Bland-Altman with repeated measures and Deming Regression with bootstrap resampling. Secondary effectiveness included evaluation across all Fitzpatrick Scales with all three devices (Presygen™/si-1, Kent Camera and T.Ox™ Tissue Oximeter). Presygen™/si-1 and Kent Camera results from this study should be interpreted with caution due to the small sample size and the influence of unusual values from the Kent camera with several observations.

Clinical Study 2 Results:
Results of this study were as follows: StO_2 values with Presygen™/si-1 and T.Ox™ Tissue Oximeter shows equivalence across all Fitzpatrick Scales including within the higher melanin scales of II-V with all of the observations within the Limits of Agreement on the Bland-Altman plot (Table 1). Results of Presygen™/si-1 versus Kent Camera were limited to Fitzpatrick I and II. The %StO2 results measurement range was 67% to 90%.

Clinical Study 2 VOT Results:
For the VOT study, Presygen™/si-1, Kent Camera and T.Ox™ Tissue Oximeter all demonstrate similar fluctuations in response to ischemia and reperfusion in the measurement of $\%StO_2$. Data from the vascular occlusion test shows $\%StO_2$ stable at baseline, decreasing through ischemia and rebounding during reperfusion for both Presygen™/si-1 and Kent Camera, and between Presygen™/si-1 and T.Ox™ Tissue Oximeter.

Clinical Study 2 VOT Re-analysis:
Reanalysis of Clinical Study 2 VOT data was conducted as described above for Clinical Study 1 VOT Re-analysis. The Bland-Altman plot shows most of the data is centered close to a Mean Bias that is close to 0; 90% of the observations are within the Limits of Agreement. It should be noted that the paired VOT measurements were collected on two different arms and at separate time intervals which generates an additional source of variation. Bland-Altman analysis showed a mean difference of 0.016 %StO2 with Limits of Agreement (-8.563, 8.596). The analysis of the correlation between the ΔStO2 by Deming regression shows equivalence with intercepts that are close to 0 and slopes that are close to 1. Deming Regression Analysis showed an intercept of 0.00 %StO2 with a 95% CI (-0.423, 0.401) and a slope of 0.815 with a 95% CI (0.716, 0.937). The histogram plot demonstrates that the differences in the ΔStO2 are distributed evenly around 0.

Throughout the study there was no SAE or AE observed.

In conclusion, the weight of the evidence from both clinical study 1 and study 2 shows that Presygen™/si-1 and Kent Camera have consistent directional temporal $\%StO_2$ changes, particularly during the VOT. Presygen™/si-1 compared to the Kent camera in Fitzpatrick Scale I with >95% of the observations within the Limits of Agreement on the Bland-Altman plot and the Deming regression results showing a slope with 95% confidence limits including 1 (Study 1). The intercept for the Deming regression equation did not contain 0 however, demonstrating a small positive bias in the measurement of $\%StO_2$. Presygen™/si-1 showed equivalence to Kent Camera in subjects with minimal tissue melanin. These studies shows equivalence between Presygen™/si-1 and T.Ox™ Tissue Oximeter $\%StO_2$ measurements overall, and within each Fitzpatrick Scale, demonstrating that Presygen™/si-1 shows equivalence with the reference device measurement of $\%StO_2$ across Fitzpatrick Scales I through V and is not significantly affected by tissue melanin.

Table 3. Y-Intercept and Slope from Deming Regression for Presygen vs. Reference Device in Clinical Study 1 vs. Study 2

	Clinical Study 1	Clinical Study 2
Y-Intercept (95% agreement)	119.803 (98.08, 151.617)	-0.590 (-21.244, 16.253)
Slope (95% agreement)	-0.734 (-1.204, -0.399)	1.007 (0.788, 1.278)

Table 4. Summary Table of Bland-Altman Data for Presygen vs. Reference Device in Clinical Study 1 vs. Study 2

	Clinical Study 1	Clinical Study 2
Bias (%StO2), (95% agreement)	6.4595 (4.25, 8.67)	0.1 (-1.64, 1.84)
LOA (%StO2)	-31.45, 44.37	-10.65, 10.85
RMSE (%StO2)	20.35	5.38

9. CONCLUSIONS

The information presented in this 510(k) submission demonstrates that the Presygen™/si-1 is substantially equivalent to the predicate device.