



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 24, 2016

Novarix Limited
c/o Ms. Deirdre Barrow
Senior Regulatory Affairs Consultant
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816 Congress Avenue, Suite 1400
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Re: K152088
Trade/Device Name: Iv-eye
Regulation Number: 21 CFR 880.6970
Regulation Name: Liquid crystal vein locator
Regulatory Class: I
Product Code: KZA
Dated: December 10, 2015
Received: December 10, 2015

Dear Ms. Barrow:

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 contact the Division of Industry and Consumer Education 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>. 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 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 Industry and Consumer Education 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,

 Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152088

Device Name

IV-eye

Indications for Use (Describe)

The IV-eye is a hand-held, non-invasive imaging device that assists medical personnel, trained in vascular access procedure, to identify and locate suitable peripheral veins for the purposes of cannulation and venipuncture.

The IV-eye should only be used in conjunction with standard techniques of visualization and palpation in assessing and locating veins.

The IV-eye is intended only for skin contact via a disposable single use cover.

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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K152088
510(k) Summary
for
IV-eye

1. Submission Sponsor

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3. Date Prepared

January 5th, 2016

4. Device Identification

Trade/Proprietary Name:	IV-eye
Common/Usual Name:	device, vein location, liquid crystal
Classification Name:	Liquid crystal vein locator
Classification Regulation:	21 CFR 880.6970
Product Code:	KZA
Device Class:	Class I
Classification Panel:	General Hospital

5. Legally Marketed Predicate Device(s)

Table 5A: Legally Marketed Predicates

Device Name	510(k) No.	Product Code	Classification Regulation	Sponsor
IR Viewer	K042679	KZA	21 CFR 880.6970	Infrared Imaging System
VTS1000 (Veinsite)	K101838	KZA	21 CFR 880.6970	VueTek Scientific

6. Device Description

The IV-eye is a hand-held, battery powered electronic non-invasive imaging device that assists medical personnel, trained in vascular access procedure, to identify and locate suitable peripheral veins for the purposes of cannulation and venipuncture. The IV-eye transmits near infrared light into a patient's tissue at a wavelength of 850nm. As the light hits a vascular structure it is absorbed by the hemoglobin in the blood, whereas it passes through other tissue.

The camera in the device captures the light that has passed through the patient and, in identifying the blocked light and applying a number of algorithms, the IV-eye is able to produce an image on its LCD display of the patient's vascular structure directly underneath the device. This appears as a darker color to the contrasting tissue. The picture is updated in real-time and is close to actual size. Trained medical personnel can use the image of the patient's vascular structure to assist them in choosing a suitable vein for cannulation and venipuncture.

The IV-eye is intended to be used only by trained medical personnel to assist them in locating suitable veins for venipuncture and cannulation. It does not differentiate between arteries and veins and should therefore only be used in conjunction with standard techniques of locating veins. Other than regular cleaning and replacement of batteries, the IV-eye requires no routine or preventative maintenance.

The IV-eye includes a single-use cover which prevents the lower casing and wings of the device having direct contact with the patient, and is intended to reduce cross-contamination risk in using the device. The IV-eye is intended only for skin contact via this disposable single use cover.

7. Indication for Use Statement

The IV-eye is a hand-held, non-invasive imaging device that assists medical personnel, trained in vascular access procedure, to identify and locate suitable peripheral veins for the purposes of cannulation and venipuncture.

The IV-eye should only be used in conjunction with standard techniques of visualization and palpation in assessing and locating veins.

The IV-eye is intended only for skin contact via a disposable single use cover.

8. Substantial Equivalence Discussion

Table 5A compares the IV-eye to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing detailed information regarding the basis for the determination of substantial equivalence.

One key difference between the proposed device and the predicate device, IR viewer, is that the proposed device and the other predicate, VTS1000 (Veinsite), are handheld and the IR viewer is not hand held. The IR Viewer is a much larger piece of equipment which is on a roll stand comprised of a nIR camera, computer and display screen with touchscreen controls. This technological characteristic difference is not considered to negatively impact the substantial equivalence argument as it does not raise new questions with regard to safety and effectiveness. It has been shown in this 510(k) that the IV-eye device is substantially equivalent in its function as a non-invasive medical device that assists medical personnel, trained in vascular access procedure, to identify and locate suitable peripheral veins for the purposes of cannulation and venipuncture.

The proposed device shares the same intended use as the predicate devices but has a more limited indication for use in that the IV-eye is indicated for veins only whereas the predicate devices are indicated for peripheral vessels. The proposed device clearly falls within the intended use of the predicate devices therefore this difference in indications for use does not impact the substantial equivalence argument.

A potential difference exists between the devices in terms of patient contacting materials, however, it has been established in this 510(k) through appropriate biocompatibility testing that the device does not introduce any new concerns regarding safety of the patient contacting materials. Therefore it can be assumed that any potential differences will not impact the substantial equivalence argument.

The IR viewer predicate product allows the option for a sterile single use disposable light source whereas the proposed IV-eye product and the VTS1000 do not. The proposed device contraindicates against the use of the device on broken or damaged skin and the skin contacting element of the IV-eye device is for single use only. It is noted that the IR viewer also includes the option of a non-sterile single use disposable patient contacting element. Therefore the use of single-use non-sterile patient contacting material in the proposed device does not raise new questions with regard to safety and effectiveness and the device is deemed substantially equivalent to the predicate devices.

The proposed device and both predicates are digital units however the proposed IV-eye and VTS1000 device are battery operated units and the predicate device, IR viewer is AC powered. This difference does not impact the device operation and the overall technical and functional capabilities as demonstrated by appropriate bench testing and compliance with appropriate international standards.

In summary, the IV-eye device shares the same intended use, similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate device. The IV-eye is similar in function to the predicate devices for the modes of operation and use as each device is intended to be used in conjunction with standard techniques of visualization and palpation in assessing and locating veins. The design of the predicates differ somewhat from each other and from that of the proposed device, however each device is non-invasive and utilizes infrared red light of the same wavelength, the proposed device and that of the IR-viewer are patient contacting but both devices use a disposable unit for the patient contacting element.

The differences in design do not affect performance, or raise different questions of safety and effectiveness as demonstrated through bench and clinical testing provided in support of this 510(k).

Table 5A – Device Comparison Chart: Similarities and Differences to predicate device

Manufacturer	Novarix Limited	Infrared Imaging System	VueTek Scientific	Significant Differences
Trade Name	IV-eye	Originally IR viewer now known as Vascular Viewer™	VTS1000 (Veinsite)	
510(k) Number	n/a	K042670	K101838	N/A
Product Code	KZA	KZA	KZA	Same
Regulation Number	880.6970	880.6970	880.6970	Same
Regulation Name	Liquid crystal vein locator.	Liquid crystal vein locator.	Liquid crystal vein locator.	Same
Intended Use	Intended Use is to indicate the location of blood vessels	Intended Use is to indicate the location of blood vessels	Intended Use is to indicate the location of blood vessels	Same
Indications for Use	<p>The IV-eye is a hand-held, non-invasive imaging device that assists medical personnel, trained in vascular access procedure, to identify and locate suitable peripheral veins for the purposes of cannulation and venipuncture.</p> <p>The IV-eye should only be used in conjunction with standard techniques of visualization and palpation in assessing and locating veins.</p> <p>The IV-eye is intended only for skin contact via a disposable single use cover.</p>	<p>The IR Viewer is a non-invasive, electronic device for visualization of patient vasculature to supplement normal, line-of-sight viewing of vascular structures.</p> <p>It is indicated for use in procedures for inserting a needle or catheter in superficial, peripheral vessels.</p>	<p>The VTS 1000 is a non-invasive electronic device to aid in the visualization of superficial vasculature. It is indicated for use during procedures requiring vascular or peripheral vessel access.</p>	<p>No Significant Difference; the differences between them are:</p> <ul style="list-style-type: none"> • The IR viewer is not hand held; it is a Digital (solid state) device on a roll stand comprised of a nIR camera, computer and display screen with touchscreen controls. • Both predicates are indicated for peripheral vessels whereas the IV-eye is a subset of this indication as it is indicated for Veins only. • General differences in the choice of

Manufacturer	Novarix Limited	Infrared Imaging System	VueTek Scientific	Significant Differences
Trade Name	IV-eye	Originally IR viewer now known as Vascular Viewer™	VTS1000 (Veinsite)	
				wording
Patient Contacting Material	Disposable cover: Non-Woven fabric ,Clear LDPE Film and Hypoallergenic contact adhesive Device cover: Plastic	Foil backing that seals to the skin and hydrogel adhesive	Unknown	No known significant difference
Sterile	No, patient contact area covered by single use disposable covers	The single use disposable light source (DLS) is provided in both a sterile and non-sterile format	No – device is not a patient contacting device	No Significant differences; the differences between them are the fact that: <ul style="list-style-type: none"> • The IR viewer predicate product allows the option for a sterile single use disposable light source whereas the proposed IV-eye product and the VTS1000 do not. • VTS1000 is not a patient contacting device while the IV-eye and the IR viewer include a non-sterile single use disposable patient contacting element.
Single-Use	No – disposable cover is a single use but device is a multiple use device	No – disposable light source is a single use but device is a multiple use device	No	No significant difference

Manufacturer	Novarix Limited	Infrared Imaging System	VueTek Scientific	Significant Differences
Trade Name	IV-eye	Originally IR viewer now known as Vascular Viewer™	VTS1000 (Veinsite)	
Shelf Life	2 Years	Unknown	Unknown	Unknown; predicate device shelf life is not available
Light Source	Infrared light via a LED of wavelength 850nm	Infrared light via a LED of wavelength 850nm	Infrared light via a LED of wavelength 850nm	No difference
Battery Operated	Yes - 2 x 1.5v AA alkaline batteries that are not suitable for recharging whereas the IV-viewer is plugged into the mains	No	Yes sealed 7.4V lithium ion rechargeable battery	All units are digital units however the proposed IV-eye and VTS1000 device are battery operated units and the predicate device is AC powered
AC Powered	No	Yes	No	All units are digital units however the proposed IV-eye and VTS1000 device are battery operated units and the predicate device is AC powered
Complies with ISO 10993-1	Yes	Unknown	Unknown	No known difference
Electrical Performance Testing Passed	Yes	Yes	Yes	No difference

9. Non-Clinical Performance Data

The following testing has been performed successfully to support substantial equivalence:

- Biocompatibility;
 - ISO 10993-1: 2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing
 - ISO 10993-5: 2009, Biological Evaluation of Medical Devices - Part 5: Test for In Vitro Cytotoxicity
 - ISO 10993-10: 2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity
- Laser Performance;
 - EN 60825-1: 2007, Safety of Laser Products - Part 1: Equipment Classification and Requirement
- Electrical Performance;
 - IEC 60601-1: 2005, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance
 - EN 60601-1-2: 2007, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- Environmental & Transportation – ISTA 1A
- Cleaning
- Mechanical Testing

As part of demonstrating the acceptable performance of the IV-eye and in showing substantial equivalence to the predicate device, Novarix completed a number of tests. The IV-eye meets all the requirements for overall design, biocompatibility, laser and electrical performance and Novarix has confirmed that the output meets the design inputs and specifications. The IV-eye passed all testing stated above as shown by the acceptable results obtained.

The device passed all the testing in accordance with national and international standards including those referenced above and IEC 62366-2007 and IEC 62304:2006. International standards associated with risk management; ISO 14971-2012 and labelling symbols; ISO 15223-1:2012 were also employed to ensure the IV-eye device is safe and effective.

10. Clinical Performance Data

A clinical study was performed on 30 healthy volunteers with different BMI, gender and skin color and age to examine the performance characteristics of the IV-eye with regards to:

1. Demonstrating the ability of the IV-eye in identifying peripheral veins suitable for venipuncture and cannulation
2. Quantify the measurement depth capability of the IV-Eye in relation to the depth capability of the predicate VeinSite device from VueTek in order to establish equivalence.

Results of the clinical investigation support the indications for use of the IV-eye to identify and locate suitable peripheral veins for the purposes of cannulation and venipuncture and

confirmed that the device can be considered equivalent to the Veinsite device from VuTek in terms of performance.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics, but can be demonstrated to be substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the IV-eye and the predicate devices do not raise any new questions regarding its safety and effectiveness. The IV-eye, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.