February 24, 2016

Novarix Limited
c/o Ms. Deirdre Barrow
Senior Regulatory Affairs Consultant
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
K152088
510(k) Summary
for
IV-eye

1. Submission Sponsor

Novarix Limited
The Core Business Centre
Milton Hill
Abingdon
Oxfordshire, OX13 6AB
United Kingdom
Phone: +44 (0)1235 828 292
Fax: +44 (0)1235 861 041
John Scott, Chief Executive Officer

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: 00 353 86 8733815
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Deirdre Barrow, Senior Consultant, RA
Email: project.management@emergogroup.com

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

<table>
<thead>
<tr>
<th>Device Name</th>
<th>510(k) No.</th>
<th>Product Code</th>
<th>Classification Regulation</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>IR Viewer</td>
<td>K042679</td>
<td>KZA</td>
<td>21 CFR 880.6970</td>
<td>Infrared Imaging System</td>
</tr>
<tr>
<td>VTS1000 (Veinsite)</td>
<td>K101838</td>
<td>KZA</td>
<td>21 CFR 880.6970</td>
<td>VueTek Scientific</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Manufacturer</th>
<th>Novarix Limited</th>
<th>Infrared Imaging System</th>
<th>VueTek Scientific</th>
<th>Significant Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Name</strong></td>
<td>IV-eye</td>
<td>Originally IR viewer now known as Vascular Viewer™</td>
<td>VTS1000 (Veinsite)</td>
<td></td>
</tr>
<tr>
<td><strong>510(k) Number</strong></td>
<td>n/a</td>
<td>K042670</td>
<td>K101838</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Product Code</strong></td>
<td>KZA</td>
<td>KZA</td>
<td>KZA</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Regulation Number</strong></td>
<td>880.6970</td>
<td>880.6970</td>
<td>880.6970</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Regulation Name</strong></td>
<td>Liquid crystal vein locator.</td>
<td>Liquid crystal vein locator.</td>
<td>Liquid crystal vein locator.</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Intended Use</strong></td>
<td>Intended Use is to indicate the location of blood vessels</td>
<td>Intended Use is to indicate the location of blood vessels</td>
<td>Intended Use is to indicate the location of blood vessels</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Indications for Use</strong></td>
<td>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.</td>
<td>The IR Viewer is a non-invasive, electronic device for visualization of patient vasculature to supplement normal, line-of-sight viewing of vascular structures. It is indicated for use in procedures for inserting a needle or catheter in superficial, peripheral vessels.</td>
<td>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.</td>
<td>No Significant Difference; the differences between them are:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Both predicates are indicated for peripheral vessels whereas the IV-eye is a subset of this indication as it is indicated for Veins only.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• General differences in the choice of</td>
</tr>
</tbody>
</table>

Table 5A – Device Comparison Chart: Similarities and Differences to predicate device
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Novarix Limited</th>
<th>Infrared Imaging System</th>
<th>VueTek Scientific</th>
<th>Significant Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name</td>
<td>IV-eye</td>
<td>Originally IR viewer now known as Vascular Viewer™</td>
<td>VTS1000 (Veinsite)</td>
<td>wording</td>
</tr>
<tr>
<td>Patient Contacting Material</td>
<td>Disposable cover: Non-Woven fabric, Clear LDPE Film and Hypoallergenic contact adhesive Device cover: Plastic</td>
<td>Foil backing that seals to the skin and hydrogel adhesive</td>
<td>Unknown</td>
<td>No known significant difference</td>
</tr>
</tbody>
</table>
| 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:  
  • 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. |
<p>| 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 |</p>
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Novarix Limited</th>
<th>Infrared Imaging System</th>
<th>VueTek Scientific</th>
<th>Significant Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trade Name</strong></td>
<td>IV-eye</td>
<td>Originally IR viewer now known as Vascular Viewer™</td>
<td>VTS1000 (Veinsite)</td>
<td></td>
</tr>
<tr>
<td><strong>Shelf Life</strong></td>
<td>2 Years</td>
<td>Unknown</td>
<td>Unknown</td>
<td>Unknown; predicate device shelf life is not available</td>
</tr>
<tr>
<td><strong>Light Source</strong></td>
<td>Infrared light via a LED of wavelength 850nm</td>
<td>Infrared light via a LED of wavelength 850nm</td>
<td>Infrared light via a LED of wavelength 850nm</td>
<td>No difference</td>
</tr>
<tr>
<td><strong>Battery Operated</strong></td>
<td>Yes - 2 x 1.5v AA alkaline batteries that are not suitable for recharging whereas the IV-viewer is plugged into the mains</td>
<td>No</td>
<td>Yes sealed 7.4V lithium ion rechargeable battery</td>
<td>All units are digital units however the proposed IV-eye and VTS1000 device are battery operated units and the predicate device is AC powered</td>
</tr>
<tr>
<td><strong>AC Powered</strong></td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>All units are digital units however the proposed IV-eye and VTS1000 device are battery operated units and the predicate device is AC powered</td>
</tr>
<tr>
<td><strong>Complies with ISO 10993-1</strong></td>
<td>Yes</td>
<td>Unknown</td>
<td>Unknown</td>
<td>No known difference</td>
</tr>
<tr>
<td><strong>Electrical Performance Testing Passed</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No difference</td>
</tr>
</tbody>
</table>
9. Non-Clinical Performance Data

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

- Biocompatibility;
  - 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;

- Electrical Performance;
  - IEC 60601-1: 2005, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance

- 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. Quantifying 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.