FEB 18 2011

Pre-Market Notification 510(k) Summary

K101838

1. Sponsor Information:

Company Name & Address:	VueTek™ Scientific PO Box 665 25 Northbrook Drive Gray, Maine 04039 USA
Contact Person:	Douglas A. Moran
Contact Title:	Executive Vice President
Contact Phone Number:	(207) 657-6525
Contact Fax Number:	(207) 657-6582
Date of Summary:	June 11, 2010

2. Device Name and Classification:

Common and Usual Name:	Vein Locator
Proprietary Name:	VTS1000
Classification Name:	Device, Vein Location, Liquid Crystal
Classification Regulation:	21 CFR 880.6970
Regulatory Class:	Class 1
Product Code:	KZA
Performance Standards:	No applicable performance standards have been issued under section 514 or under section 513(b) of the Food, Drug and Cosmetic Act.

3. Predicate Device(s):

Vustik® (Vustik, Inc.)
Head Mounted Display (Vista Medical)

4. Description of Device:

The VueTek Scientific™ VTS1000 is a near-infrared (NIR) emitter, video acquisition, and head mounted display (HMD) device that affords viewing of superficial, subcutaneous vasculature, by differentiating it with higher contrast from surrounding tissue. Visualization of vascular structures is provided by a portable headset display system which supplements normal line of sight viewing during vascular access procedures. The VTS1000 device does not replace the accepted conventional vascular identification and confirmation methods used by qualified professionals.

5. **Indications for Use:**
The VTS1000 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.

6. **Comparison with Predicate Device(s):**
The VTS1000 is substantially equivalent when compared to the identified predicate devices.

7. **Performance Summary:**
Clinical, non-clinical, and independent testing performance data were submitted that demonstrated that the VTS1000 met design requirements and is safe and effective for its intended use. The VTS1000 conforms to IEC60601-01, IEC60601-1-2, CIE-S009/IEC-62471, ANSI IESNA RP 27.1, 27.2 and 27.3.

Clinical study results involving subjects with ages from <4 weeks to >65 years of age of varying genders, ethnicity, weight, and skin tone, demonstrated that the VTS1000 effectively provided and enhanced visualization of superficial, subcutaneous vascular structures when compared to the naked eye. The device was additionally found to be safe, portable, flexible, and provided normal line-of-sight viewing during use.

The performance data demonstrated that the VTS1000 met the established user and design requirements and performs safely and effectively as designed, for its intended use.

8. **Conclusions:**
The VTS1000 was determined to be substantially equivalent with similar devices currently legally commercially available.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vuetek Scientific LLC
C/O Mr. Paul Sumner
Arkin Consulting Group
1733 Canton Lane, Suite B
Marietta, Georgia 30062-2679

FEB 18 2011

Re: K101838
Trade/Device Name: VTS1000
Regulation Number: 21 CFR 880.6970
Regulation Name: Liquid Crystal Vein Locator
Regulatory Class: I
Product Code: KZA
Dated: February 4, 2011
Received: February 7, 2011

Dear Mr. Sumner:

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.

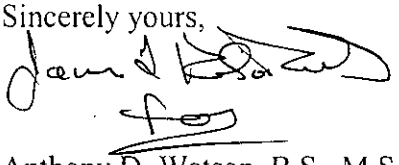
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: VTS1000

Indications For Use:

The VTS1000 is a non-invasive electronic device to aid in the visualization of superficial vasculature. It is indicated for use in procedures requiring vascular or peripheral vessel access.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

2/18/2011

510(k) Number: K101838