



Food and Drug Administration  
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January 6, 2016

Vascular Insight, LLC  
c/o Lorraine Hanley  
Vice President, Regulatory Affairs  
1 Pine Hill Drive  
Two Batterymarch Park  
Suite 100  
Quincy, MA 02169

Re: K153502

Trade/Device Name: ClariVein IC  
Regulation Number: 21 CFR 870.1210  
Regulation Name: Continuous Flush Catheter  
Regulatory Class: Class II  
Product Code: KRA  
Dated: December 1, 2015  
Received: December 7, 2015

Dear Ms. Hanley:

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 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>. 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,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K153502

Device Name

ClariVein IC

Indications for Use (Describe)

The ClariVein IC is indicated for infusion of physician specified agents in the peripheral vasculature.

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.\***

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**510(k) SUMMARY (Page 1 of 3)**

**Device Name:** ClariVein® IC

**Date Prepared:** 6 January 2016

**A. Submitter/Sponsor**

Vascular Insights, LLC.  
1 Pine Hill Drive,  
Two Batterymarch Park  
Suite 100  
Quincy, MA 02169  
Telephone Number/Fax: 617-519-1109/203-350-0311  
Contact Person: Lorraine M. Hanley, Vice President Regulatory Affairs

**B. Device Name**

Trade Name:	ClariVein® IC
Common/Usual names:	Intravascular Catheter, Infusion Catheter, Cannula
Classification Names:	Continuous Flush Catheter
Regulation Number	21 CFR§870.1210
Classification:	Class II
ProCode	KRA

**C. Predicate Device(s)**

510(k)	ClariVein® IC K071468
Common/Usual names:	Intravascular Catheter, Infusion Catheter, Cannula
Classification Names:	Continuous Flush Catheter
Regulation Number	21 CFR§870.1210
Classification:	Class II
ProCode	KRA

**D. Device Description**

The ClariVein IC is a specialty infusion catheter with 360° rotatable fluid dispersion wire connected to a proximally located integral battery powered motor drive unit (MDU). The MDU includes the speed selector, handle grip and syringe support features which facilitate physician-controlled infusion of the selected agent. The ClariVein IC is introduced through a microintroducer. Utilizing vascular imaging, the coaxial catheter sheath with dispersion wire is navigated through the vasculature to the treatment site. Fluid delivered through the catheter assembly's infusion port, surrounds the dispersion wire and exits via an opening at the distal end of the catheter. The ClariVein IC has no user serviceable parts or capital equipment. It is provided to the user sterile, for single patient use and is fully disposable.

**E. Indication For Use**

The ClariVein® IC is indicated for infusion of physician specified agents in peripheral vasculature.

**F. Technology Characteristics**

The ClariVein IC is a sterile, single use, low profile infusion catheter available in multiple lengths and configurations for physician selection. Its distally located catheter assembly, including the catheter shaft and a 360° rotatable dispersion wire, is connected to the proximally located motor drive unit (MDU) powered by an integral, self-contained 9V battery and circuitry. Infusion is through an opening at the distal end of the catheter and the fluid delivery is enhanced by use of a rotating dispersion wire to deliver the infused fluid into the vessel and to the vessel wall. The rate of rotation of the dispersion wire is physician determined and controlled via the MDU's speed selector. The device provides the user with four optional dispersion wire rotation speeds (RPM); i.e. 2,000 (Low), 2,500 (Medium), 3,000 (Medium-High) and 3,500 (High). Wire rotation is physician-controlled by selecting the desired rotation speed and depressing the trigger. The ClariVein IC is provided with labeling which presents instruction for the safe and effective use of the device.

The ClariVein IC is manufactured of materials demonstrated to be biocompatible for its intended use. The ClariVein IC is not made with phthalate material or natural rubber latex. The ClariVein product does not include medicants. There are no user serviceable parts or capital equipment. The device is entirely disposable upon completion of the procedure.

**G. Performance Data**

The ClariVein IC has been assessed in accordance with relevant industry standards, FDA recognized standards, and FDA Guidance documents. The product has been determined to meet all relevant parts of the following industry standards and guidance documents:

ISO 10555-1 Singular Use Intravascular Catheter	ISO 11607-1 Packaging
ISO 10993-1, -4, -5, -7, -10, -11 Biocompatibility	ISTA 2A - Transportation
IEC 60601-1 3 <sup>rd</sup> Ed. – Electrical Safety	ISO 11135-1 - Sterilization
IEC 60601-2 – Electromagnetic Compatibility (EMC)	ISO 15223-1, EN 1041, Labeling
ISO 11070 Sterile single use intravascular introducers, dilators and guidewires	

**Summary of Nonclinical Tests**

Nonclinical testing was performed on the ClariVein IC to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during testing. Testing included the follow:

**Biocompatibility**

Hemocompatibility - Hemolysis Direct/Indirect Contact	Hemocompatibility-Coagulation Unactivated Partial Thromboplastin Time	Cytotoxicity L929 Natural Red Uptake
Hemocompatibility Thrombogenicity	Irritation/Sensitization Kligman Maximization	Irritation/Sensitization Intracutaneous Reactivity
Systemic Toxicity (acute) Materials Mediated Rabbit Pyrogen	Systemic Toxicity - Acute	Systemic Toxicity (acute) Materials Mediated Rabbit Pyrogen

**510(k) SUMMARY (Page 3 of 3)****Performance Testing**

Visual Quality Test demonstrates that there are no extraneous materials.	Corrosion Test demonstrates that there are no signs of corrosion.	Labeling Nominals Test demonstrates that labeling meets unit expressions.
Peak Tensile Tests: Distal Tip to Sheath Hub to sheath at strain relief Hub to Guide Wing Female coupling to male coupling Male coupling to motor drive shaft Wire to female coupling Test demonstrates that all joints meet requirements.	Dispersion Wire Tests: Tensile Fatigue Test demonstrates that all joints meet requirements.	Simulated Use Test demonstrates functionality in a simulated fixture.
Liquid leak under pressure Test demonstrates no leakage	Wire rotation Speed Test demonstrates required rotation speed.	Torque Force to drive train Test demonstrates torque requirements.
Syringe and check valve functionality Test demonstrates compatible functionality.		

**H. Clinical Testing**

Not applicable.

**I. Animal Testing**

Not applicable.

**J. Conclusion**

Responses to questions posed in the FDA's *Substantial Equivalence Decision Flow Chart* lead to a determination of "substantial equivalence" for the subject ClariVein IC.

The ClariVein IC is substantially equivalent to the predicate in the following aspects:

- **Design, Function and Manufacture** – the subject and predicate devices are substantially equivalent to the technological characteristics of both designs. The predicate ClariVein IC is available in 45 and 65 cm lengths; the proposed ClariVein IC introduces an 85 cm length device.
- **Materials** – There are no new materials used between the predicate and proposed devices.
- **Indications** – Both the predicate and proposed devices have identical indications for use.
- **Packaging** – The subject and predicate devices utilize similar packaging configurations using industry accepted materials.
- **Sterilization** – The subject and predicate devices are both sterilized utilizing a validated EO sterilization process in accordance to ISO 11135.
- **Labeling** – Both the subject and predicate device have similar labeling.

Testing was conducted to show that no new risks were identified and that the performance profile is similar to the well-established predicate device cleared for market.