January 18, 2019

Innovative Health, LLC
Amanda Babcock
Principal Regulatory Affairs Specialist
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K181126
Trade/Device Name: Reprocessed Visions PV .035 Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: December 17, 2018
Received: December 19, 2018

Dear Amanda Babcock:

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,

Jessica E. Paulsen -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

The item numbers included in the scope of this submission are as follows:

Description	Item Number	French Size	Guide Wire	Minimum Sheath	Length (cm)
Visions PV .035 Digital IVUS Catheter	88901	7	0.035" – 0.038"	8.5 F	90

Table 1: Device Scope

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)*

K181126

Device Name
Reprocessed Visions PV .035 Digital IVUS Catheter

Indications for Use *(Describe)*

The Reprocessed Visions PV .035 catheter is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. The Visions PV .035 ultrasound imaging catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

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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SECTION 5: 510(k) SUMMARY

As required by 21 CFR 807.92(c)

Submitter's Name and Address:
Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257

Contact Name and Information:
Amanda Babcock
Principal Regulatory Affairs Specialist
Innovative Health, LLC.
(480) 525-5911 (office)
(888) 965-7705 (fax)
ababcock@innovative-health.com

Date prepared:
April 26, 2018

Device Information:

Trade/Proprietary Name:	Reprocessed Visions PV .035 Digital IVUS Catheter
Common or Usual Name:	Ultrasonic Imaging Catheter
Classification Name:	Diagnostic Intravascular Catheter
Classification Number:	Class II, 21 CFR 870.1200
Product Code:	OWQ

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K153094	Visions PV .035 Digital IVUS Catheter	Volcano Corporation

Device Description:
The Reprocessed Visions PV .035 catheter is an over-the-wire intravascular imaging catheter with a digital ultrasound transducer at the distal end. The transducer utilizes a 64-element cylindrical array that radiates acoustic energy into the surrounding tissue and detects the subsequent echoes. The information from the echoes is used to generate real-time images of the peripheral vessels.

The catheter is introduced percutaneously or via surgical cutdown into the vascular system, and it is designed to track over 0.035"-.038" (0.89-0.97mm) guide wires.

The catheter has body markers 1 cm apart along the working length. There are 25 radiopaque markers on the distal end of the catheter, starting 1cm from the imaging plane, with the 25th RO marker overlapping the distal most wide inked marker. Inked markers (non-radiopaque) continue along the shaft, spaced 1 cm apart, middle-to-middle, with wider marks indicating 5 cm intervals.

The Visions PV .035 catheters may only be used with Volcano s5 Series and CORE Series of Systems.

A hydrophilic coating is applied externally to a distal portion of the catheter.

The item numbers in scope of this submission are as follows:

Description	Item Number	French Size	Guide Wire	Minimum Sheath	Length (cm)
Visions PV .035 Digital IVUS Catheter	88901	7	0.035" – 0.038"	8.5 F	90

Table 5.1: Device Scope

Indications for Use:
The Reprocessed Visions PV .035 catheter is designed for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such vessels. The Visions PV .035 ultrasound imaging catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Catheter are identical to the predicate devices. There are no changes to the claims, clinical applications, patient populations, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of the Catheter includes removal of visible soil and decontamination. Each device is inspected and function tested prior to packaging and labeling.

Functional and Safety Testing:
Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Visions PV .035 Catheter. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional testing
    - Visual Inspection
    - Dimensional Verification
    - Simulated Use
    - Mechanical Characteristics
    - Hydrophilic Coating
    - System Compatibility
- Packaging Validation

The catheter is reprocessed no more than one (1) time. Each device is marked and tracked. After the device has reached the maximum number of reprocessing cycles, the device is rejected from further reprocessing. Reprocessing is performed only by Innovative Health. Innovative Health restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:
Innovative Health concludes that the Reprocessed Visions PV .035 Catheter is as safe and effective as the predicate devices described herein.