May 25, 2022

Innovative Health, LLC.
Christina Fleming
VP, Compliance and Regulatory Affairs
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K210655
Trade/Device Name: Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: April 23, 2022
Received: April 25, 2022

Dear Christina Fleming:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

The item number included in the scope of this submission is as follows:

Description	Item Number	French Size	Guide Wire	Minimum Sheath	Length (cm)
Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter	85900P	3.5F	0.014”	0.056”	150

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210655

Device Name
Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter

Indications for Use *(Describe)*
The Reprocessed Eagle Eye Platinum RX Digital IVUS Catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Reprocessed Eagle Eye Platinum RX Digital IVUS Catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

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
PRAStaff@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."

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:
Christina Fleming
VP, Compliance and Regulatory Affairs
Innovative Health, LLC.
(480) 525-5972 (office)
(888) 965-7706 (fax)
tfleming@innovative-health.com

Date prepared:
March 3, 2021

Device Information:

Trade/Proprietary Name:	Reprocessed Eagle Eye Platinum RX 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
K143701	Eagle Eye Platinum Digital IVUS Catheter	Volcano/Phillips Corporation

Reference Device:

510(k) Number	510(k) Title	Manufacturer
K200195	NES Reprocessed Visions PV .014P RX Digital IVUS Catheter	Northeast Scientific, Inc.

510(k) Number	510(k) Title	Manufacturer
K181126	Reprocessed Visions PV .035 Digital IVUS Catheter	Northeast Scientific, Inc.

Device Description:
The Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter incorporates a cylindrical ultrasound transducer array. The array 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 coronary and peripheral vessels.

The Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter utilizes an internal lumen that allows the catheter to track over the 0.014" (0.36 mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The catheter is introduced percutaneously or via surgical cut down into the vascular system.

Three 1 mm-long radiopaque markers are incorporated on the internal lumen positioned 10 mm apart from distal edge to distal edge, starting 10 mm from the proximal edge of the portion of the scanner marker tube normally visible under fluoroscopy.

The Eagle Eye Platinum RX Digital IVUS Catheters are exclusive use with Volcano s5 Series and CORE Series of Systems. This catheter will not operate if connected to any other imaging system.

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)
Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter	85900P	3.5F	0.014”	0.056”	150

Table 1: Device Scope

Indications for Use:
The Reprocessed Eagle Eye Platinum RX Digital IVUS Catheters are designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. The Reprocessed Eagle Eye Platinum RX Digitial IVUS Catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Eagle Eye Platinum RX Digital IVUS 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, the 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 by reference to demonstrate performance (safety and effectiveness) of Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional testing
    - Visual Inspection
    - Dimensional Verification
    - Simulated Use
    - Mechanical Characteristics
    - Hydrophilic Coating
    - System Compatibility
- Drying Validation
- 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. Innovative Health restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:
Innovative Health concludes that the Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter is as safe and effective as the predicate devices described herein.