May 12, 2025

Northeast Scientific, Inc.
Matthew Farley
Director of Product Development
2142 Thomaston Ave
Waterbury, Connecticut 06704

Re: K250592
Trade/Device Name: NES Reprocessed Visions PV .018 Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ, OBJ
Dated: February 20, 2025
Received: February 27, 2025

Dear Matthew Farley:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 S. Deoras -S

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

Description	Item Number	French Size	Guide Wire	Minimum Sheath	Length (cm)
Volcano Visions PV .018 Digital IVUS Catheter	86700	3.5F	0.018"	6F	135 cm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250592

Device Name
NES Reprocessed Visions PV .018 Digital IVUS Catheter

Indications for Use *(Describe)*
The NES Reprocessed Visions PV .018 Digital IVUS Catheter is 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 NES Reprocessed Visions PV .018 Digital IVUS Catheter is 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.

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SECTION 5: 510(k) SUMMARY

As required by 21 CFR 807.92(c)

Submitter's Name and Address:
Northeast Scientific, Inc. (NES)
2142 Thomaston Ave.
Waterbury, CT 06704

Contact Name and Information:
Matt Farley
Director of Product Development
Northeast Scientific, Inc.
203-756-2111 (office)
203-757-5532 (fax)
matt@smarthealth-care.com

Date Prepared:
February 27th, 2025

Device Information:

Trade/Proprietary Name:	NES Reprocessed Visions PV .018 Digital IVUS Catheter
Common or Usual Name:	Diagnostic intravascular catheter
Classification Name:	Reprocessed Intravascular Ultrasound Catheter
Classification Number:	Class II, 21 CFR 870.1200
Product Code:	OWQ/OBJ
510(k) Number:	K250592

Predicate Device:

510(k)	510(k) Title	Manufacturer	Product Code
K150442	Volcano Visions PV .018 Digital IVUS Catheter	Volcano Corporation	OBJ

Table 5.1 – Predicate Device

Device Description:
The NES Reprocessed Visions PV .018 Digital IVUS Catheter utilizes a cylindrical ultrasound transducer array close to the distal tip to radiate acoustic energy into the surrounding tissue. By using the information gathered from the ultrasonic echoes, the device can generate real-time images of the coronary and peripheral vessels.

The NES Reprocessed Visions PV .018 Digital IVUS Catheter tracks over a 0.018" (0.46mm) guide wire by through an internal lumen. Approximately 31 cm from the catheter tip is a guidewire port for the exiting guidewire. The NES Reprocessed Visions PV .018 Digital IVUS Catheter is introduced into the vascular system percutaneously or via surgical cutdown.

The NES Reprocessed Visions PV .018 Digital IVUS Catheter may only be used with the Volcano s5 Series or CORE Series of Systems Operator's Manual. If connect to another system, the catheter will not operate.

The NES Reprocessed Visions PV .018 Digital IVUS Catheter is intended to be reprocessed one (1x) time.

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

Description	Item Number	French Size	Guide Wire	Min. Sheath	Length (cm)
Volcano Visions PV .018 Digital IVUS Catheter	86700	3.5F	0.018"	6F	135 cm

Table 5.2 – Device Scope

Indications for Use:

The NES Reprocessed Visions PV .018 Digital IVUS Catheter is 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 NES Reprocessed Visions PV .018 Digital IVUS Catheter is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Technological Characteristics:

The NES reprocessed device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device. There are no changes to the claims, clinical applications, patient populations, performance specifications, or method of operation.

Functional and Safety Testing:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the NES Reprocessed Visions PV .018 Digital IVUS Catheter. The test methods, requirements and acceptance criteria used for the .018 IVUS are the same used in cleared K200195 (reprocessed .014 IVUS). The .014 IVUS is a different model in the same family as the NES Reprocessed Visions PV .018 Digital IVUS Catheter and has the same indications. This included the following:

- Cleaning Validation
- Sterilization Validation
- Functional testing
    - Visual Inspection
    - Dimensional Verification
    - Simulated Use
    - Mechanical Characteristics
    - System Compatibility
    - Image Acuity
    - Transducer Acoustic Output
    - Transducer Thermal Testing
    - Flushing Adapter Compatibility
    - Surface Property Testing
- Drying Validation
- Packaging Validation
- Biocompatibility Testing

The catheter is reprocessed no more than one (1) time. Each device is marked during reprocessing. After the device has reached the maximum number of reprocessing cycles, the device is rejected from further

reprocessing. Reprocessing is performed only by Northeast Scientific. Northeast Scientific restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:
Northeast Scientific, Inc. concludes that the NES Reprocessed Visions PV .018 Digital IVUS Catheter is as safe and effective as the predicate devices described herein.