June 22, 2020

Northeast Scientific, Inc.
Matthew Farley
Director, Regulatory & Quality
2142 Thomaston Ave.
Waterbury, Connecticut 06704

Re: K200195
Trade/Device Name: NES Reprocessed Visions PV .014P RX Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: May 21, 2020
Received: May 22, 2020

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 (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,


Mark Fellman
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 510(k) submission are as follows:

| Description | Item Number | French Size | Guide Wire | Minimum Sheath | Length (cm) |
|---|---|---|---|---|---|
| NES Reprocessed Visions PV .014P RX Digital IVUS Catheter | 014R | 3.5F | 0.014” | 5F | 150 cm |

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)*
K200195

Device Name
NES Reprocessed Visions PV .014P RX Digital IVUS Catheter

Indications for Use *(Describe)*
The NES Reprocessed Visions PV .014P RX 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 .014P RX 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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**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, Regulatory & Quality
Northeast Scientific, Inc.
203-756-2111 (office)
203-757-5532 (fax)
matt@smarthealth-care.com

**Date Prepared:**
December 30th, 2019

**Device Information:**

| | |
|---|---|
| Trade/Proprietary Name: | NES Reprocessed Visions PV .014P 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 |
| 510(k) Number: | K200195 |

**Predicate Device:**

| 510(k) Number | 510(k) Title | Manufacturer |
|---|---|---|
| K152829 | Visions PV.014P RX Digital IVUS Catheter | Volcano Corporation |

Table 5.1 – Predicate Device

**Device Description:**
The NES Reprocessed Visions PV .014P 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 NES Reprocessed Visions PV .014P 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 cutdown 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 VISIONS PV .014P catheter may only be used with the Volcano s5 Series or CORE Series of Systems Operator's Manual. 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) |
|---|---|---|---|---|---|
| Visions PV.014P RX Digital IVUS Catheter | 014R | 3.5F | 0.014" | 5F | 150 cm |

Table 5.2 – Device Scope

**Indications for Use:**
The NES Reprocessed Visions PV .014P RX 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 .014P RX 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 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, Northeast Scientific's reprocessing of the Catheter includes removal of visible soil and decontamination. Each device is inspected and functionally tested prior to packaging and labeling.

**Functional and Safety Testing:**
Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the NES Reprocessed Visions PV .014P RX Digital IVUS Catheter. This included the following:

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

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 .014P RX Digital IVUS Catheter is as safe and effective as the predicate devices described herein.

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.014P RX Digital IVUS Catheter | 014R | 3.5F | 0.014” | 5F | 150 cm |

Table 1: Device Description