July 1, 2022

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

Re: K220171
Trade/Device Name: NES Reprocessed 0.9mm Turbo Elite Laser Atherectomy Catheter
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal artery stripper
Regulatory Class: Class II
Product Code: QTF
Dated: June 3, 2022
Received: Jume 6, 2022

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,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*

K220171

Device Name
NES Reprocessed 0.9mm Turbo-Elite Laser Atherectomy Catheter

Indications for Use *(Describe)*
The NES Reprocessed 0.9mm Turbo-Elite Laser Atherectomy Catheter (0.014"guidewire compatible and over-the-wire configuration) is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions.

The 0.014" Over-the-wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

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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The Reprocessed Device Models in scope of K220171 are as follows:

Description	Item Number	Guidewire Compatibility	Max Tip Diameter	Max Shaft Diameter	Working Length	Sheath Compatibility
0.9mm Turbo-Elite Laser Ablation Catheter	410-152	0.014”	0.038”	0.047”	150 cm	4 Fr.

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 Engineering
Northeast Scientific, Inc.
203-756-2111 (office)
203-757-5532 (fax)
matt@smarthealth-care.com

Date Prepared:
December 10th, 2021

Device Information:

Trade/Proprietary Name:	NES Reprocessed 0.9mm Turbo Elite Laser Atherectomy Catheter
Common or Usual Name:	Laser Atherectomy Catheter
Classification Name:	Intraluminal Artery Stripper
Classification Number:	Class II, 21 CFR 870.4875
Product Code:	QTF
510k Number:	K220171

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K170059	Spectranetics Turbo-Elite Laser Atherectomy Catheters	Spectranetics/Philips

Table 5.1 – Predicate Device

Device Description:
The NES Reprocessed Spectranetics Turbo-Elite Laser Catheters are percutaneous intravascular devices constructed of multiple optical fibers arranged around a guidewire lumen. Catheter sizing identification is printed on the catheters.

For NES Reprocessed Spectranetics Turbo-Elite Laser Catheters, Over-The-Wire (OTW) catheters, a Luer adapter located at the proximal end of the usable length facilitates the use of the laser catheter over the appropriately sized guidewire.

Mechanism of Action for Turbo-Elite Catheters:
The multifiber laser catheters transmit ultraviolet energy from the Spectranetics CVX-300 Excimer Laser to the obstruction in the artery. The ultraviolet energy is delivered to the tip of the laser catheter to photoablate lesions which may be compromised of atheroma, fibrosis, calcium, and thrombus; thus, recanalizing diseased vessels (photoablation is the process by which energy photons cause molecular

bond disruption at the cellular level without thermal damage to surrounding tissue). The Spectranetics laser catheters have a proprietary lubricious coating to ease their trackability through arteries.

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

Description	Item Number	Guidewire Compatibility	Max Tip Diameter	Max Shaft Diameter	Working Length	Sheath Compatibility
0.9mm Turbo-Elite Laser Ablation Catheter	410-152	0.014"	0.038"	0.047"	150 cm	4 Fr.

Table 5.2 – Device Scope

Indications for Use:
The NES Reprocessed 0.9mm Turbo-Elite Laser Atherectomy Catheter (0.014" guidewire compatible and over-the- wire configuration) is indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions. The 0.014" Over-the-wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

Technological Characteristics:
The purpose, design, 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. Northeast Scientific also applies a proprietary lubricious hydrophilic coating to facilitate movement through the arteries. 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 0.9mm Turbo-Elite Laser Atherectomy Catheter. This included the following:

- Cleaning Validation
- Sterilization Validation
- Functional testing
    - Visual Inspection
    - Dimensional Verification
    - Simulated Use
    - Mechanical Characteristics
    - Hydrophilic Coating
    - System Compatibility
    - Solarization
    - Tissue Ablation
- 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 0.9mm Turbo-Elite Laser Atherectomy Catheter is substantially equivalent to the predicate devices described herein.