March 27, 2018

Northeast Scientific, Inc. (NES)
Mr. Matthew Farley
Directory of Regulatory & Quality Engineering
2142 Thomaston Avenue
Waterbury, Connecticut 06704

Re: K173214
Trade/Device Name: NES Reprocessed RF Stylet (Model # R-RFS2-6-12)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: March 6, 2018
Received: March 7, 2018

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173214

Device Name
NES Reprocessed RF Stylet (RFS), model # R-RFS2-6-12

Indications for Use *(Describe)*
The NES Reprocessed RF Stylet (RFS) is intended for use in vessel and tissue coagulation including:
- Treatment of incompetent (i.e. refluxing) perforator and tributaiy veins.

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 NES Reprocessed RF Stylet (RFS) (model # R-RFS2-6-12) is a reprocessed Covidien ClosureRFS™ Endovenous Radiofrequency (RF) Stylet (model # RFS2-6-12) subject to clearance

Device Model	Device Name	OEM
RFS2-6-12	ClosureRFS™ Endovenous Radiofrequency (RF) Stylet	Covidien

510(k) Summary

I. SUBMITER

Northeast Scientific, Inc.
2142 Thomaston Avenue
Waterbury, CT 06704

Phone: 203-756-2111
Fax: 203-757-5532

Contact Person: Matthew Farley
Date Prepared: August 23, 2017

II. DEVICE

Name of Device: NES Reprocessed RF Stylet (RFS), NES model # R-RFS2-6-12
Common or Usual Name: Bipolar Electrosurgical Instrument
Classification Name: Electrosurgical Devices (21 CFR §878.4400)
Regulatory Class: II
Product Code: NUJ
Reprocessing Cycles: The device will be reprocessed a maximum of one time.

III. PREDICATE DEVICE

VNUS RFS (ClosureRFS Endovenous Radiofrequency Stylet, model # RFS2-6-12), 510(k) # K052003

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The NES Reprocessed RF Stylet (RFS) is a reprocessed VNUS RFS (510(k) # K052003). The device is a high frequency electrosurgical system designed for blood vessel and tissue coagulation in general surgical procedures. This device's energy source comes from a compatible and separately cleared Radiofrequency (RF) Generator. The device has been validated to be reprocessed a maximum of one time.

The NES Reprocessed RF Stylet (RFS) is provided sterile (EtO) and is a single use, disposable device. The device is used in a healthcare facility. The device's function is to deliver RF energy to the desired treatment site and relay temperature and other information to the RF Generator. The device consists of one model.

The device itself consists of the stylet shaft, handle and cable. A sharp is included with the device for patient insertion. The tip of the stylet serves to deliver the RF energy to the desired treatment site while the cable plugs into the RF generator (for power and relay temperature/other feedback). The tip, inner and outer lumen are the only patient-contacting parts. The patient-contacting material is as follows: AISI 304 SST, 302 SST and polyimide. All patient-contacting material has proven to be biocompatible. The non patient-contacting material is as follows: poly methyl methacrylate and polypropylene. The device is compatible with the software in the separately cleared Radiofrequency (RF) Generator. The NES Reprocessed RF Stylet (RFS) is considered an external communicating device with circulating blood contact for a duration of less than 24 hours.

V. INDICATIONS FOR USE

The NES Reprocessed RF Stylet (RFS) is intended for use in vessel and tissue coagulation including:

- Treatment of incompetent (i.e., refluxing) perforator and tributary veins.

Note: The indications for use are identical to the predicate's indications for use as seen below.

VI. INDICATIONS FOR USE OF PREDICATE DEVICE

The VNUS RFS is intended for use in vessel and tissue coagulation including:

- Treatment of incompetent (i.e., refluxing) perforator and tributary veins.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The NES Reprocessed RF Stylet (RFS) and its predicate, VNUS RFS, are substantially equivalent in technological characteristics. Both stylet devices share identical design, material, chemical composition and energy sources. Both stylet devices share identical clinical applications, performance specifications, clinical procedures and patient population. The NES Reprocessed RF Stylet (RFS) and the predicate use the same temperature, power and impedance ranges during the treatment cycle. There are no changes made to the design, material, chemical composition or energy sources of the VNUS RFS when reprocessed to the NES Reprocessed RF Stylet (RFS). NES does provide the user with a new sharp that has a slightly different material composition (different poly plastics in non patient-contacting parts), however, it has been shown to have substantial equivalence in function and form when compared to the sharp supplied with the predicate. The device itself, however, does not undergo any design, material, chemical composition or energy source changes.

VIII. PERFORMANCE DATA

Functional:
Functional testing was completed on the NES Reprocessed RF Stylet (RFS) post reprocessing. No errors or warning were observed during the cycles for all of the tested devices. This indicates that the device functions properly after being clinically used, shipped and reprocessed.

Design Validation:
The instructions for use, product label, packaging card, NES sharp, sharp cap, pouch, retail box and shipping box were all evaluated by a user and expert of the device to ensure all of the components of the NES Reprocessed RF Stylet (RFS) meet the user needs and to ensure that NES provides a device capable of meeting the Indications for Use. Based on the findings of the user, it has been determined that the NES Reprocessed RF Stylet (RFS) device and all of its components have been properly designed for meeting the user's needs and Indications for Use.

Biocompatibility Testing:
Biocompatibility testing was completed on the NES Reprocessed RF Stylet (RFS). The battery of testing included the following tests: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity and Hemocompatibility.

Based on the results, the device does not elicit any anatomical reactions as the device passed the cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity and hemolysis studies. This shows that the device is biocompatible.

Electromagnetic Safety and Electromagnetic Compatibility (EMC):
An EMC study was competed on the NES Reprocessed RF Stylet (RFS) post reprocessing. It was found that the device passed both emissions and immunity testing. Based on the results, the NES Reprocessed RF Stylet (RFS) is electromagnetic compatible.

Cleaning:
A cleaning validation was completed for the NES Reprocessed RF Stylet (RFS). The battery of testing included the following tests: TOC Levels post reprocessing, Protein Levels post reprocessing, Hemoglobin Levels post reprocessing, Bioburden (Aerobic, Anaerobic, Yeast and Mold) Levels post reprocessing and Bacterial Endotoxin Levels post reprocessing.

Based on the results, the NES Reprocessed RF Stylet (RFS) is cleaned properly after being clinically used and reprocessed.

Drying:
The drying validation for the NES Reprocessed RF Stylet (RFS) was completed to ensure complete drying after the devices had gone through the wet processes of cleaning. It was found that the NES Reprocessed RF Stylet (RFS) can be properly dried.

Packaging/Shelf Life:
A packaging/shelf life validation was completed on the NES Reprocessed RF Stylet (RFS). The battery of testing included the following tests: Seal Peel Strength at low sealing parameters, Seal Peel Strength at high sealing parameters, Seal Peel Strength after conditioning and distribution simulation, Bubble Leak Test after conditioning and distribution simulation, Seal Peel Strength after accelerated aging and Bubble Leak Test after accelerated aging.

Based on the findings from the results, the NES Reprocessed RF Stylet (RFS) is packaged and sealed properly to maintain a sterile barrier and capable of withstanding distribution, conditioning and its shelf life.

Sterilization:
A sterilization validation was completed on the NES Reprocessed RF Stylet (RFS). It was found that the NES Reprocessed RF Stylet (RFS) can be properly sterilized and has an acceptable level of residual Ethylene Oxide (EtO) post sterilization.

Sharp Verification:
Based on the results, the NES 600053 RFS Sharp is designed similar to the OEM sharp in design, fit, strength and function. Based on these findings, the NES 600053 RFS Sharp is substantially equivalent to the OEM sharp.

Note: All equipment used in the testing of the NES Reprocessed RF Stylet (RFS) had been properly calibrated prior to use.

IX. CONCLUSIONS

Based upon the similarities found in the indications for use, design, material, chemical composition, energy source and function between the NES Reprocessed RF Stylet (RFS) and the marketed predicate device (VNUS RFS, K052003) and efficacy of the NES Reprocessed RF Stylet (RFS) reprocessing process, it is concluded that the NES Reprocessed RF Stylet (RFS) is substantially equivalent to the predicate device. The predicate device has a well-established history of safe and efficacious use.