K090661

510 (K) Summary

Date Prepared: 18 August 2009

510(k) number: K090661

Applicant Information:

Northeast Scientific, Inc.
29 S. Commons Road
Waterbury, CT 06704

Contact Person: Craig Allmendinger
Phone: 203-756-2111
Fax: 203-757-5532

Device Information:
Classification: Class II
Trade Name: NES Reprocessed Varicose Vein RF Catheter
Classification Name: Electrosurgical Device (21 CFR § 878.4400)
Product Code: NUJ

Device Description: NES Reprocessed Varicose Vein RF Catheters are specially designed electrosurgical catheters. RF (radiofrequency) energy is delivered to an intravascular catheter in order to heat a blood vessel to a predetermined heat and coagulate that blood vessel. NES Reprocessed Varicose Vein RF Catheters incorporate a hand-piece, a flexible shaft and a distal tip section containing the RF (radiofrequency) electrode.

Predicate Device: The NES Reprocessed Varicose Vein RF Catheter is substantially equivalent in intended use and operation to the "VNUS® ClosureFast™ Catheter, Model CF7-7-60 (K061373)"

Intended Use: NES Reprocessed Varicose Vein RF Catheters are intended for endovascular coagulation of blood vessels in patients with superficial vein reflux.

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Performance Data:	Bench, laboratory and animal testing was conducted to demonstrate performance (safety and effectiveness) of NES Reprocessed Varicose Vein RF Catheters. This included the following tests: • Biocompatibility • Validation of Reprocessing • Sterilization Validation • Function Test(s) • Packaging Validation Performance testing on animals demonstrates that NES Reprocessed Varicose Vein RF Catheters perform as originally intended
Conclusion:	Northeast Scientific, Inc. concludes that the reprocessed catheters are safe, effective and substantially equivalent to the predicate device as described herein.
Standards:	IEC60601-1, IEC60601-2-2, IEC60601-1-2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Northeast Scientific, Inc.
% Mr. Craig Allmendinger
Chief Executive Officer
29 South Commons Road
Waterbury, Connecticut 06704

Re: K090661
Trade/Device Name: NES Reprocessed Varicose Vein RF Catheter
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: May 25, 2010
Received: May 26, 2010

Dear Mr. Allmendinger:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William H. Maisel, MD, MPH
Deputy Center Director of Science
Center for Devices and
Radiological Health

Enclosure

List of Model(s): NES Reprocessed Varicose Vein RF Catheter

INDICATIONS FOR USE STATEMENT PAGE (IFU)

Company: Northeast Scientific, Inc.

Device Name: NES Reprocessed Varicose Vein RF Catheter

Device Size: CF7-7-60cm

510k #: K090661

INDICATIONS FOR USE

The NES Reprocessed Varicose Vein RF Catheter is intended for endovascular coagulation of blood vessels in patients with superficial vein reflux

Prescription use ✓ (Part 21 CFR 801 subpart D) AND/OR Over the counter Use _____ (21 CFR 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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