K060676

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**Section 2-1** **510(k) Summary**

**Submitter**

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

SEP - 7 2007

**Contact**

Craig Allmendinger
President & CEO
Phone: 203-756-2111
Fax: 203-757-5532
Email: Allmendinger@sbcglobal.net

**Date**

August 31st, 2007

**Device**

**Trade Name:** NES Reprocessed Endoscopic Trocar
**Common Name:** Non-Bladed Trocar
**Classification Name:** Endoscope and accessories
**Product Code:** NLM
**Device Class:** Class II
**OEM Models:** Ethicon XCEL B5LT

**Predicate Devices**

| 510(k) # | Trade Name |
|---|---|
| K011538: | Endopath® Non-Bladed Solid Obturator Trocar |
| K011257: | Endopath® Non-Bladed Obturator Trocar System (5mm) |
| K990028: | Endopath® Optiview® Optical Surgical Obturator and Sleeve |
| K971738: | Ethicon Endopath® Resposable Trocar System |
| K922608: | Endopath® EP Disposable Surgical Trocar |

**Indications for Use**

NES Reprocessed Endoscopic Trocars are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures.

**Contraindications**

NES Reprocessed Endoscopic Trocars are not intended to be used on patients undergoing open surgical procedure and for whom endoscopic procedure has been contraindicated.

**Device Description**

Trocars are devices inserted into a patient in order to maintain a clear pathway to facilitate the insertion of various surgical tools. Trocars are designed in both bladed and non-bladed configurations, however this submission is for non-bladed B5LTs. Non-bladed trocars require an incision be made before insertion into the patient's cavity. Trocars have a luer stopcock port for insufflation and desufflation of the patient's cavity. NES

| | |
|---|---|
| | Reprocessed Endoscopic Trocars are sent from a user facility to be cleaned, sterilized and repackaged by NES. NES Reprocessed Endoscopic Trocars have the same intended use and performance characteristics equivalent to Endoscopic Trocars provided by Original Equipment Manufacturers (OEM). |
| **Technological Characteristics** | NES Reprocessed Endoscopic Trocars have identical design, materials, characteristics and intended use as the OEM Trocars. |
| **Test Data** | NES Reprocessed Endoscopic Trocars operate as originally intended and are safe, effective and sterile as demonstrated by cleaning, packaging, performance, sterilization and biocompatibility testing. |
| **Conclusion** | Based on the information provided, NEScientific, Inc. concludes that NES Reprocessed Endoscopic Trocars are safe, effective, perform as intended and are substantially equivalent to the predicate devices identified herein. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2007

Northeast Scientific, Inc.
% Mr. Craig Allmendinger
President & CEO
29 South Commons Road
Waterbury, Connecticut 06704

Re: K060676
Trade/Device Name: NES Reprocessed Endoscopic Trocar
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NLM
Dated: August 8, 2007
Received: August 9, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): K060676

Device Name: NES Reprocessed Endoscopic Trocar

Indications For Use:

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060676

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**K060676**

## List of Reprocessed Device(s):

| Description | Model Number | Size (ID/Length) |
|---|---|---|
| Ethicon XCEL Bladeless Endoscopic Trocar | B5LT | 5 mm diameter x 100 mm |