



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Endius, Inc.
Ms. Susan Finneran
Manager, Quality Assurance and Regulatory Affairs
23 West Bacon Street
Plainville, MA 02762

JUL 27 2015

Re: K992535
Trade/Device Name: Endius Suction/Irrigation Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated (Date on orig SE ltr): July 28, 1999
Received (Date on orig SE ltr): July 29, 1999

Dear Ms. Finneran,

This letter corrects our substantially equivalent letter of September 1, 1999.

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 contact 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>. 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K992535

510(k) Number (if known):

Device Name: Endius Suction /Irrigation Device

Indications for Use: The Endius Suction/ Irrigation Device is intended to be used to irrigate and aspirate fluid during Endoscopic and open spinal procedures

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use X
(Per 21 CFR 801.109)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K992535

Section 6 - 510(k) Summary of Safety and Effectiveness

6.1 Statement This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

6.2 Submitter Endius, Inc.
23 West Bacon Street
Plainville, MA. 02762

6.3 Company Contact Susan Finneran
QA/ RA Manager
508-643-0983

6.4 Device Name **Proprietary Name:** Endius Suction/Irrigation Instrument
Common Name: Endoscopic Suction/ Irrigation Device
Classification Name: Endoscope and Accessories

6.5 Predicate Legally Marketed Devices EndoSI™ Suction/Irrigation Trumpet Valve and Accessories

6.6 Device Description The Endius Endoscopic Irrigation/ Suction Device is intended to be used to irrigate and aspirate fluids during Endoscopic and open spinal Procedures and therefore to assist in the visualization. The device consists of a single -use disposable tubing set/trumpet valve which is intended to be attached to a re-usable suction/irrigation attachment.

6.7

**Device
Indications and
Intended use**

The Endius Suction /Irrigation Device is intended to be used to irrigate/aspirate fluids during Endoscopic and open spinal surgical procedures.

6.8

**Substantial
Equivalence**

The Endius Endoscopic Spinal Access System is substantially equivalent to the EndoSI™ Suction/Irrigation Trumpet Valve and Accessories

Table of Substantial Equivalent Device Similarities		
Device Name	EndoSI™ Suction/Irrigation Device	Endius Suction/Irrigation Device
Intended use	Irrigation and Aspiration of fluid during laparoscopic procedures	Irrigation and Aspiration of fluid during Endoscopic Spinal procedures.
Materials	PVC, ABS	PVC, ABS, Delrin
Sterilization Methods	Sterile components sterilized by gamma irradiation	Sterile components sterilized by gamma irradiation
Product Labeling	Trumpet Valve: Sterile, single use Suction/Irrigation attachment: Sterile, single use	Trumpet Valve: Sterile, single use Suction/Irrigation attachment: Non-Sterile, re-usable
Packaging	Sterile components packaged in Tyvek pouch	Sterile components packaged in Tyvek pouch

Applicant



Date

7/27/99