5. 510(K) SUMMARY

APR - 7 2010

K093279

Proprietary Name: NAVIX Access Device

Classification Name: KOG - endoscope and/or accessories

Common Name: Access Device

Manufacturer: Xlumena, Inc.
453 Ravendale Drive, Suite H
Mountain View, California 94117

Contact: Witney McKiernan, RN, MSN
Director of Business & Clinical Affairs
Xlumena, Inc.
453 Ravendale Drive, Suite H
Mountain View, California 94117
(650) 961-9900 x225
Fax: (650) 961-9900
wmckiernan@xlumena.com

Preparation Date: October 16, 2009

Predicate Devices:

The NAVIX Access Device is substantially equivalent to the following currently marketed predicate devices:

(1) Electrocautery Dilation Balloon – K082114
Approved December 19, 2008
Apollo Endosurgery, Inc.
Product Code: KNS
Regulation: Sec.876.4300 Endoscopic electrosurgical unit and accessories

(2) Wilson-Cook Cystotome – K022595
Approved October 17, 2002
Wilson-Cook Medical Inc.
Product Code: KNS
Regulation: Sec.876.4300 Endoscopic electrosurgical unit and accessories

Device Description:

The NAVIX Access Device is a multi-lumen catheter device that enables the physician to create and dilate an access tract through adjacent tissues. The NAVIX Access Device is exchange-free in that it delivers multiple tools without the need to exchange these tools over a guidewire. The NAVIX Access Device includes a trocar, an anchor balloon, and a dilation balloon.

Intended Use:

The NAVIX Access Device is intended for use as an accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract during endoscopic procedures.

Technological Characteristics of Substantial Equivalence:

The NAVIX Access Device is substantially equivalent to the:

(1) Electrocautery Dilation Balloon – K082114
Approved December 19, 2008
Apollo Endosurgery, Inc.
Product Code: KNS
Regulation: Sec.876.4300 Endoscopic electrosurgical unit and accessories

(2) Wilson-Cook Cystotome – K022595
Approved October 17, 2002
Wilson-Cook Medical Inc.
Product Code: KNS
Regulation: Sec.876.4300 Endoscopic electrosurgical unit and accessories

with regard to materials, safety and efficacy.

Performance Data:
Xlumena performed an analysis of key characteristics of predicates in comparison to key characteristics of the NAVIX Access Device. This analysis has shown that the NAVIX Access Device is substantionally equivalent in characteristics and uses to our predicate devices in combination.

Design durability was tested in the laboratory, and animal studies were used to validate performance of the system in a simulated clinical environment as well as verify the performance to design specifications.

Conclusion:
The NAVIX Access Device has the same intended use and utilizes the same fundamental scientific technology as that of the referenced predicate devices.

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

APR - 7 2010

Ms. Witney Mckiernan, RN, MSN
Director of Business and Clinical Affairs
Xlumena
453 Ravendale Drive, Suite H
MOUNTAIN VIEW CALIFORNIA 94043

Re: K093279
Trade/Device Name: NAVIX Access Device
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 24, 2010
Received: March 29, 2010

Dear Ms. Mckiernan:

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 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ___Not known at this time___X____

Device Name: NAVIX Access Device

Indications for Use:

The Xlumena NAVIX Access Device is intended for use as an accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst, when it is visibly bulging into the gastrointestinal tract during endoscopic procedures.

Prescription Use ____X (for the trained endoscopist only)___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)
Page __ of ___
(POSTED NOVEMBER 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093279