K124052
pg. 1 of 2

SECTION 1.0: 510(k) SUMMARY

FEB 26 2013

1.1 MANUFACTURER / REGISTRATION INFORMATION

Lake Region Medical
340 Lake Hazeltine Drive
Chaska, MN 55318-1029 USA
FDA REGISTRATION NUMBER: 2126666

Contact Person: Tracy Meyer
Title: Regulatory Specialist
Telephone: 952-641-8510
Fax: 952-448-3441

1.2 TRADE NAME (PROPRIETATY NAME)

NAVIPRO™ Guidewire

1.3 DEVICE COMMON NAMES/USUAL NAMES/CLASSIFICATION NAMES

These devices are commonly known as guides, Guidewires, or spring Guidewires. The current classification names and product codes are Gastroenterology/Urology (OCY).

1.4 CLASS OF DEVICE

This type of Guidewire was originally listed as a Class II device by the Gastroenterology/Urology (OCY) review panel.

1.5 IDENTIFICATION OF PREDICATE DEVICE(s)

510(k) Number	Manufacturer	Device Name
K081708	Lake Region Medical	Taxi Endoscopic Guidewire
K000011	Lake Region Medical	Hydrophilic Coated Guidewire (ZIPwire)

1.6 DEVICE DESCRIPTION

Utilizing proprietary processes, these guides are constructed from a steerable, metallic core (Nitinol) with a polymer jacket (polyurethane) coating. A hydrophilic coating is applied over the radiopaque polymer jacket. Guidewires are available in 260cm length and in diameters 0.018", 0.025" and 0.035" depending on specific design requirements. Guidewires may have a straight or a pre-shaped distal tip and are available in different tip flexibilities, which are dependent on the grind configuration of the core.

OUTSIDE DIAMETER:	.018", .025" and .035"
LENGTHS:	260 cm
TIPS:	Standard, Stiff

1.7 COMPLIANCE WITH APPLICABLE STANDARDS

The NaviPro™ Guidewire is in compliance with ISO 10993, ISO 11070, ISO 15223, EN 980, ISO 594.

SECTION 1.0: 510(k) SUMMARY

1.8 INTENDED USE STATEMENT

The endoscopic guidewire is intended for use in selective cannulation of the biliary ducts including, but not limited to the common bile, pancreatic, cystic, right and left hepatic ducts. The endoscopic guidewire is designed to be used during endoscopic pancreatic -biliary procedures for catheter introduction and exchanges of catheters, cannulas and sphicterotomes.

1.9 CONTRAINDICATIONS

None Known

1.10 COMPARISON

The NaviPro™ Guidewire is substantially equivalent to the Taxi Endoscopic Guidewire with 510(k) number K081708 with desgin changes.
The design is of the NaviPro™ is substantially equivalent to the Hydrophilic Coated (ZIPwire) Guidewire with 510(k) K000011.

1.11 QUALIFICATION TESTING

The conclusions drawn from non-clinical and biocompatibility testing demonstrate the device is as safe, as effective and performs as safely and effectively as the legally marketed device.

NON-CLINICAL TESTING

In order to demonstrate the safety and effectiveness of the NaviPro™ Guidewire, Lake Region Medical performed testing to establish requirements. Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes. The results of these tests demonstrated the functionality and performance characteristics of these guidewire are comparable to the similar currently marketed devices. See section 13.0 for the results.

BIOCOMPATIBILITY TESTING

Risk analysis concluded that there was no additional biocompatibility testing required.

1.12 SUBSTANTIAL EQUIVALENCE DATA

The NaviPro™ Guidewire has a similar intended use as Taxi Endoscopic Guidewires legally marketed by Lake Region Medical and cleared by 510(k) K081708.

The NaviPro™ Guidewire is the exact same design as the ZIPwire, with a different intended use, legally marketed by Lake Region Medical and cleared by 510(k) K000011.

The NaviPro™ Guidewire has the exact same physical characteristics as the secondary predicate device (ZIPwire). The safety and effectiveness of these differences have been proven in the aforementioned Qualification Testing.

The NaviPro™ Guidewire is substantially equivalent to the Taxi Endoscopic Guidewires cleared under 510(k) K081708 and to the ZIPwire cleared under 510(k) K000011. All test results support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 26, 2013

Lake Region Medical
% Ms. Tracy Meyer
Regulatory Specialist
340 Lake Hazeltine Drive
CHASKA MN 55318

Re: K124052
Trade/Device Name: NaviPro™ Guidewire
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: December 28, 2012
Received: December 31, 2012

Dear Ms. Meyer:

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,

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

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K124052

DEVICE NAME: NaviPro™ Guidewire

INDICATIONS FOR USE:

The endoscopic guidewire is intended for use in selective cannulation of the biliary ducts including, but not limited to the common bile, pancreatic, cystic, right and left hepatic ducts. The endoscopic guidewire is designed to be used during endoscopic pancreatic-biliary procedures for catheter introduction and exchanges of catheters, cannulas and sphicterotomes.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K124052