Section 5.0: 510(k) Summary

5.1 Administrative Information

JAN 0 3 2013

Name:	NeoMetrics, Inc.
Address:	2605 Fernbrook Lane North, Suite J Plymouth, MN 55447
Contact Person:	Gene Champeau
Title:	President
Phone:	(763)-559-4440
Fax:	(763) 559-7676
FDA Registration Number:	2135342
Date:	December 17, 2012

5.2 Device Information

Name of Device:	Neo ERCP Guidewire
Common Name:	Endoscopic Guidewire
Classification Name:	Endoscopic Guidewire, Gastroenterology – Urology (876.15)
Product Code:	OCY

5.3 Predicate Device Information

The following commercially available guidewire is a predicate device for Neo ERCP Guidewire.

510(k) Number	Trade or Model Name	Manufacturer
K922302	JagWire	Boston Scientific Corp.

5.4 Device Description

The Neo ERCP Guidewire is constructed of a core wire of nickel titanium based alloy, a proximal polymer jacket and a radiopaque distal tip. It also features a hydrophilic coating and either straight or angled distal tip configurations. The distal end of the guidewire has a radiopaque distal tip (10cm). The wire family has two models, the Phantom refers to .025" OD models and the Palomino refers to .035" OD models. Both the Phantom and Palomino come in 260cm and 480cm lengths.

5.5 Intended Use

The Neo ERCP Guidewire is intended for use in selective cannulation of the biliary ducts including the common bile, pancreatic, cystic, right and left hepatic ducts and to aid in the placement of diagnostic and therapeutic devices during endoscopic procedures.

5.6 Differences in the Intended Use Statements

Differences in the indications for use statements between Neo ERCP Guidewire and the JagWire IFU are not significant. The JagWire IFU refers to bronchoscopic procedures. An endoscope is the tool used in bronchoscopic and endoscopic procedures. The Neo ERCP Guidewire is not indicated for use in bronchoscopic procedures.

5.7 Technological Characteristics

A comparison of the characteristics of the proposed device to the predicate device shows the proposed device to have the following same or similar technological characteristics to the device which has received 510(k) clearance:

- Same intended use;
- Same operating principle;
- Same shelf life and sterilization process;
- Similarities in Design, Material Types, and Technology include:
    - Nominal diameters: 0.025" and 0.035"
    - Similar Lengths: 260 & 480 cm
    - Nitinol alloy core wires
    - Distal radiopaque polymer tip
    - Lubricious coatings

To ascertain similarity, the following performance testing was conducted on both the proposed device and the predicate devices:

- FDA Coronary and Cerebrovascular Guidewire Guidance January 1995 sections 1, 2, 3a, 3e, 3f and 3g
- Sterile Package Integrity per ASTM F 2096-04
- Sterile Package Integrity per ASTM F 88-09
- Reverse Bend (Fatigue Failure) per ISO 11070
- Tensile testing per ISO 11070
- Fracture Resistance per ISO 11070
- Corrosion Resistance per ISO 11070
- Radiodetectability per ISO 11070
- Rail Support per NeoMetrics' test method TM-3002

Due to the destructive nature of some of the tests and the availability of predicate devices not all testing was conducted on each predicate device.

5.8 Summary of Non-Clinical Testing

Non-clinical testing of the Neo ERCP Guidewire includes bench testing, biocompatibility testing, shelf-life testing, packaging testing and sterilization evaluation. The following tests were conducted:

- Sterility
- Biocompatibility
  - Cytotoxicity
  - Sensitization
  - Intracutaneous Irritation
  - Acute Systemic Injection
- Packaging Integrity
- Device Compatibility
- Reverse Bend
- Tensile Strength
- Fracture Resistance
- Corrosion Resistance
- Dielectric Insulation
- Simulated Use
- Shelf Life

Results of this testing demonstrate that the guidewire design meets the product specifications and intended uses.

5.9 Substantial Equivalence Conclusion

The Neo ERCP Guidewire described in this 510(k) is substantially equivalent to the device listed in section 5.3. The intended use, design, material types, technology, and performance of the Neo ERCP Guidewire are equivalent to the predicate device. There are no differences between devices which would raise issues of safety or effectiveness.

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

January 3, 2013

Neometrics, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K123439
Trade/Device Name: Neo ERCP Guidewire
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: December 7, 2012
Received: December 28, 2012

Dear Mr. Job:

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,

Herbert P. Lerner

for
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

Section 4: **Indications for Use Statement**

Indications for Use

510(k) Number (if known): K123439

Device Name: Neo ERCP Guidewire

Indications for Use:

The Neo ERCP Guidewire is intended for use in selective cannulation of the biliary ducts including the common bile, pancreatic, cystic, right and left hepatic ducts and to aid in the placement of diagnostic and therapeutic devices during endoscopic procedures.

Prescription Use: X (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)

Herbert P. Lerner

(Division Sign-Off)

Division of Reproductive, Gastro-Renal, and Urological Devices

510(k) Number K123439