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

May 19, 2016

Prosurg, Inc
Ashvin Desai
Manager, Regulatory Affairs
2193 Trade Zone Blvd
San Jose, California 95131

Re: K152466
Trade/Device Name: Neo-bronchoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: April 26, 2016
Received: April 28, 2016

Dear Ashvin Desai:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152466

Device Name

Neo- Bronchoscope ™ -Digital Video Bronchoscopy System (Rigid / Flexible)

Indications for Use *(Describe)*

The Prosurg's Neo-Bronchoscope™ - Digital Video Bronchoscopy System –Rigid & Flexible (which includes Digital Video Bronchoscope, Single use Diagnostic / Operating Outer Sheath) is intended for use for endoscopic examination, diagnosis and treatment of Airways and Tracheobronchial tree, using surgical devices and accessories.

The Neo-Bronchoscope achieves its purpose by providing the user with a visual confirmation of where the tip of the endoscope is in the human anatomy. The NeoFlex – Bronchscope allows user to guide the Bronchoscope in the desired location with ease & safety.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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ProSurg

510K Summary # K152466 (Traditional 510K)

Neo- Bronchoscope™ -Digital Video Bronchoscopy System (Rigid / Flexible)

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Contact person: Ashvin Desai
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Date Summary prepared : March 30, 2016

Device Trade Name: Neo- Bronchoscope™ - Digital Video Bronchoscopy System (Rigid / Flexible)

Device Common Name: Bronchoscope (Flexible/ Rigid)

Device Classification: 21CFR 874.4680 (Class II)

Product Code: Endoscope & Accessories - EOQ

Legally Marketed Devices to which the substantially Equivalency is claimed :	Manufacturer:	Trade Name:	510K #
	Ambu A/S	Ambu aScope Ambu Monitor (21 CFR 874.4680)	K130845 EOQ

Device Description :

The Single Use Digital Video Bronchoscope design incorporates a CMOS imaging sensor and built-in LEDs (Light Emitting Diodes) or fiber optic mounted at the distal end, connecting wires along the length of the hollow tubular structure and a USB Connector at the proximal end. The distal end of the Bronchoscope containing CMOS sensor and LEDs / Fiber optic is protected by sealed, clear optical window. The NeoFlex™ – Bronchoscope , Flexible Video Bronchoscope

device with an Articulating Tip is designed with built-in fluid suction / irrigation and working channel for Micro Instrument delivery.

Indications For Use:

The Prosurg's, Neo-Bronchoscope™ -Digital Video Bronchoscopy System –Rigid & Flexible (which includes Digital Video Bronchoscope, Single use Diagnostic / Operating Outer Sheath) is intended for use for endoscopic examination, diagnosis and treatment of Airways and Tracheobronchial tree, using surgical devices & accessories.

The, Neo- Bronchoscope achieves its purpose by providing the user with a visual confirmation of where the tip of the endoscope is in the human anatomy. The Neoflex- Bronchoscope allows user to guide the Bronchoscope in the desired location with ease and safety.

Technological Characteristics:

The Neo- Bronchoscope ™ Video Bronchoscopy System consists of four main components:

(a) Digital Video Bronchoscope (Rigid / Flexible) with CMOS Sensor & Built-in LEDs / Fiber optic.

(b) Single Use, Rigid Diagnostic / Operating Outer Sheath with Suction / Irrigation / Instrument channel and a separate, dedicated channel for video Bronchoscope insertion. Or a flexible Bronchoscope with suction / Irrigation & Instrument channel with Articulating tip deflection.

(c))Laptop /Tablet computer with windows Operating System, Video Module and Video processing Software. (Commercially Available, Not supplied by Prosurg, Inc)

(d) USB 2.0 / HD / S-Video Connecting Cables. (Commercially Available, Not supplied by Prosurg, Inc)

Substantial Equivalence:

The Neo –Bronchoscope™ Digital Video Bronchoscopy System –(Rigid & Flexible) and Predicate device Ambu ascope and Ambu Monitor (Ref: K130845) are similar in design, Components, including CMOS Imaging Sensor, LED, Outer tube Handle materials & USB 2.0 Connectors. The Manufacturing & Assembly process, Product Packaging, Sterilization method & Recommended for Single use are also identical.

The proposed Indications for Use for Neo-Bronchoscope is based on Predicate device Ambu aScope & aScope Monitor (K130845). The Neo – Bronchoscope – Digital Video System is substantially equivalent to Ambu aScope. For details, please refer to Substantial Equivalence Comparison chart summary outlining Physical, functional characteristics and Indications for use.

Performance Testing : (Bench Testing)

Prosurg has conducted performance testing (Bench Evaluation- As per FDA Guidance Document) of Neo- Bronchoscope ™ device to demonstrate Safety & effectiveness and its intended use. The

Following Testing was completed to demonstrate safety & effectiveness of the proposed device for its intended use.

- Dimensional Measurements (Outer Diameter, Working Length)
- Field of View (in air)
- Image Resolution (Number of Pixels)
- Direction of View
- LED Brightness, Voltage & Current measurement.
- Tip Deflection Control Mechanism (flex) & Angle of Tip deflection
- USB Connection compatibility with Laptop / Tablet / Monitor
- Electrical Safety Test (IEC 601-1)
- Electromagnetic Compatibility (IEC 601-1-2)
- Thermal (Heat) Temperature at the Distal Tip (LED)
- Maximum Safe amount of Suction (Vacuum) testing
- Product Labeling & IFU Requirements & Accuracy
- Packaging Integrity & Sterility Assurance Test
- Accelerated Aging Test (one Year)
- Sterilization Assurance Level (ISO 11135-1:2007)
- ETO Residual Levels (ISO 10993-7:2008)
- Biocompatibility (ISO 10993-1:2009)

Conclusion:

The results of the performance testing demonstrate that proposed Neo –Bronchoscope™ Digital Video Bronchoscopy System –(Rigid & Flexible), performs as well as predicate device for its intended use and is considered safe and effective for its intended use.