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

April 29, 2016

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

Re: K152619
Trade/Device Name: Neoscope 3D ™ – 3D Digital Video Endoscopic System (Rigid/Flexible)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 30, 2015
Received: March 28, 2016

Dear Mr. 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)*
K 152619

Device Name
***NeoScope 3D™* - 3D Digital Video Endoscopic System (Rigid / Flexible)**

Indications for Use *(Describe)*

The Prosurg's Neoscope 3D™ -3D Digital Video Endoscopic System (Rigid & Flexible) is intended to provide "Real –Time" 3D images and video to surgeons for endoscopic examination, diagnosis and treatment for Minimally Invasive surgical Procedures within Abdominal and Female Reproductive organs, using surgical devices and accessories.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510K Summary # K152619: (Traditional 510K)

***NeoScope 3D* ™ - 3D Digital Video Endoscopic System (Rigid / Flexible)**

Submitter:

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Contact Person:

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Date Summary Prepared: Nov 19, 2015

Device Trade Name: Neoscope 3D™ - 3D Digital Video Endoscopic System (Rigid / Flexible)

Device common Name: Endoscopes & Accessories

Device Classification: 21CFR 876.1500 (Class II)

Product Code: Endoscope & Accessories - GCJ

Legally Marketed Devices to which the substantially Equivalency is claimed	Manufacturer:	Trade Name:	510K #
	Prosurg, Inc	NeoScope™ -Endoscopic Diagnostic & Treatment System	K042780
	Prosurg, Inc	Neoscope™ –Digital Video Endoscopy System	K120766

Device Description:

The Neoscope 3D™ -3D Digital Video Endoscope design consists of two 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 / HD Connector at the proximal end. The distal end of the 3D Endoscope containing two CMOS sensors and LEDs / Fiber optic is protected by sealed, clear window to prevent any fluid passageway within 3D Endoscope. The NeoScope flex 3D™ - Flexible Video Endoscopic device is designed with Articulating / Deflecting Distal tip controlled by lever mechanism in the handle.
The Single Use, NeoScope 3D™ - Rigid and Flexible models are provided sterile for use by physician. The Rigid Neoscope 3D is designed to provide zero (0) degree, thirty (30) degree and forty five (45) degree field of view. The Neoscope flex 3D™ Flexible endoscope is designed to provide minimum 90 degree tip deflection & field of view.

Indications For Use:

The Prosurg's Neoscope 3D™ -3D Digital Video Endoscopic System (Rigid & Flexible) is intended to provide "Real –Time" 3D images and video to surgeons for endoscopic examination, diagnosis and treatment for Minimally Invasive surgical Procedures within Abdominal and Female Reproductive organs, using surgical devices and accessories.

Technological Characteristics:

The *NeoScope 3D* ™- 3D Digital Video Endoscopic System (Rigid / Flexible) consists of four main components:
(a) Digital Video Endoscope with two CMOS Sensor & Built-in LEDs / Fiber optic in Stainless steel Tube. Or Single Use, NeoScope flex 3D- Flexible Endoscope with Articulating / Deflecting Distal Tip. (Patient Contact Item)
(b) Video Processing Module with USB 2.0 / 3.0 / HD / DVI connecting ports. (Commercially Available, Non –Patient contact item)
(c) 3D Laptop /Tablet computer with windows Operating System, 3D Monitor / 3D TV, USB 2.0 /3.0 / HD / S-Video Connecting Cables. (Commercially Available, Non- patient contact item)

The Single Use Neoscope 3D Video Endoscope consists of CMOS (2) imaging sensors & LED mounted at the distal tip. The 3D Laptop / Tablet computers is designed to power Imaging Sensors and LED. The Neoscope 3D is provided Sterile, for Single use only.

Substantial Equivalence:

The Neoscope 3D™ - 3D Video Endoscopic System (Rigid & Flexible) is substantially equivalent to Prosurg's Predicate devices NeoScope™ - Digital Video Endoscopy System (# K042780 & # K120766) . The proposed device is similar in design, materials, construction and components including CMOS Imaging Sensor, LED, Outer tube, Handle, USB 2.0 Connection, Product Packaging & Sterilization process.

The main difference between Neoscope 3D endoscopic System and predicate Neoscope System is Indications for use, However both devices are used for endoscopic diagnosis and treatment procedures. The difference between Neoscope3D and predicate devices do not alter the suitability of the proposed device for its intended use. The other difference in proposed device consists of two CMOS sensors and 3D Laptop / Tablet computer/ 3D Video Monitor & HD Connecting cable whereas predicate device consists of a single CMOS sensor, 2D Laptop / Tablet Computer / 2D Video Monitor and USB Connecting cable. 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 for Hysteroscopes & Gynecologic Laparoscopes) of Neoscope 3D™ 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 / HD Connection compatibility with 3D Laptop / Tablet / Monitor
- Electrical Safety Test (IEC 601-1)
- Electromagnetic Compatibility (IEC 601-1-2)
- Thermal (Heat) Temperature at the Distal Tip (LED)
- 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 Neoscope 3D – 3D Digital Video Endoscopic system (Rigid / Flexible) is considered safe and effective for its intended use