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

July 11, 2016

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

Re: K152511
Trade/Device Name: Neo - Arthroscope (rigid) 2.0mm/3.5mm, Outer Sheath/ Cannula, Outer Sheath/ Cannula W/ Handle, Trocar for Outersheath/ Cannula
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: June 24, 2016
Received: July 6, 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

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

Indications for Use

510(k) Number *(if known)*
K15211

Device Name
Neo- Arthroscope **™ - Single Use Digital Video Arthroscopic System**

Indications for Use *(Describe)*

The Prosurg's Neo-Arthroscope ™ -Digital Video Arthroscopic System (which includes Digital Video Arthroscope, Single use Outer Sheath is intended to provide an internal view or image of the interior of a joint through surgical opening during examination, diagnostic / operating, arthroscopic / endoscopic treatment procedures including examination, diagnostic & surgical procedures for treatment of knee, shoulder, ankle, elbow, Hip, wrist (Carpel Tunnel Syndrome), hand, TMJ (Temporal Mandibular Joint), Spine, Disc and feet (Planter fascia Release) 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)*

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510K Summary # K15211 (Traditional 510K)

***Neo- Arthroscope*™ - Single Use Digital Video Arthroscopic System**

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Tel: 408 945 4044 Fax: 408 945 1390

Date Summary Prepared : Oct 12, 2015

Device Trade Name: Neo- Arthroscope™ - Digital Video Arthroscopic System

Device common Name: Arthroscope

Device Classification: Class II

Regulation Number / Name: 21 CFR 888.1100

Arthroscope Product Code: HRX, Arthroscope

Legally Marketed Devices	Manufacturer	Trade Name:	510K#
510K # to which the substantially Equivalency is claimed	Integrated Endoscopy System	NuVis™ Arthroscope	K140903

Device Description :

The Single Use Digital Video Arthroscope design incorporates a CMOS imaging sensor and built-in

LEDs (Light Emitting Diodes) or fiber optic mounted at the distal end or in the sidewall, connecting wires along the length of the hollow tubular structure and a USB / HD Connector at the proximal end. The distal

end of the Arthroscope containing CMOS sensor and LEDs / Fiber optic is protected by sealed, clear optical window. The Single Use Neo- Arthroscope is designed to be completely isolated from irrigation and suction fluid pathways. The design of sealed distal end and proximal end of the outer sheath / cannula also prevents

any fluid or tissue contact with Neo-Arthroscope.

The Neo-Arthroscope ™- Digital Video Arthroscopic System consists of four main components:

(a) Digital Video Arthroscope with CMOS Sensor & Built-in LEDs / Fiber optic. (Patient Contact Item)
(b) Single Use, Outer Sheath / Cannula with Suction / Irrigation, a separate, dedicated channel for insertion of video Arthroscope and /or Trocar for insertion. (Patient Contact Item)
(c) Laptop /Tablet computer with windows Operating System, TV monitor module and Video processing Software. (Commercially Available, Non patient Contact Item)
(d) USB 2.0 / HD Connecting Cables. (Commercially Available, Non Patient Contact Item)

Indications For Use:

The Prosurg's Neo-Arthroscope ™ -Digital Video Arthroscopic System , which includes Digital Video Arthroscope, Single use Outer Sheath is intended to provide an internal view or image of the interior of a joint through surgical opening during examination, diagnostic / operating, arthroscopic / endoscopic treatment procedures including examination, diagnostic & surgical procedures for treatment of knee, shoulder, ankle, elbow, Hip, wrist (Carpel Tunnel Syndrome), hand, TMJ (Temporal Mandibular Joint), Spine, Disc and feet (Planter fascia Release) using surgical devices and accessories.

Summary of Technological Characteristics in comparison Predicate devices:

The Single use, Neo –Arthroscope™ Digital Video Arthroscopic System –and Predicate device Single use, NuVis™ - Digital Arthroscope (K140903) are similar in design, Components, LED lighting, Outer tube Handle materials & connecting cable to power source. The Manufacturing & Assembly process, Product Packaging, Sterilization method & Recommendations for Single use are also identical.
The Neo- Arthroscope, is similar in design, materials, packaging, sterilization and construction to NeoScope Video Endoscopy system (K120766). Both devices have identical CMOS imaging sensor & LED mounted at the distal end tip and uses Laptop / Tablet computers to power imaging Sensor and LED for endoscopic procedure. The main difference between Neo-Arthroscopic System and Neoscope System is Indications for use, However, both devices are used for endoscopic procedures for diagnosis and treatment procedure. The difference between Neo-Arthroscope and Neoscope devices do not alter the suitability of the proposed device for its intended use.

The proposed Indications for Use for Neo-Arthroscope is based on Predicate device NuVis™ Arthroscope (K140903) marketed by Integrated Endoscopy Inc. The Neo – Arthroscope, Digital Video Arthroscopic System is substantially equivalent to NuVis™ Arthroscope in design, materials, construction and use of LED for Light source. The Recommended Single use and Indications for use are also identical. For details, please refer to Substantial Equivalence matrix summary comparing Physical & functional characteristics and Indications for use.

Performance Testing : (Bench Testing)
Prosurg has conducted performance testing (Bench Test Evaluation- As per FDA Guidance Document) for of Neo-Arthroscope™ 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.
- USB / HD 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)
- 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– Arthroscope Single Use, Digital Video Arthroscopy system performs as well as predicate device and is considered safe and effective for its intended use