K131226

JUL 2 4 2014

NovaProbe®

2333 W. Main Street Suite 210 Lansdale PA 19446 Tel: 215-259-3673
http://www.NovaProbe.com Email: ingle@novaprobe.com

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter			Date of Preparation: **June 27, 2014**
Company Name/ Institution Name: **NovaProbe Incorporated**			FDA Establishment Registration Number: **3010120217**
Division Name(If Applicable) N/A			Phone Number (include area code): 215-259-3673
Street Address: 2333 W. Main Street Suite 210			FAX number (include area code): 267-295-8411
City: Lansdale	State/Province: Pennsylvania	Country: USA	Zip / Postal code 19446
Contact Person:	Manish Ingle		
Contact Title:	President		

Product Information:	
Trade Name: NOVAPROBE LED Light Source	Model number: LEUKOS 175
Common Name: Light source, Fiber Optic, Routine LED Light Source	Classification: Endoscope and Accessories, Class II (21CFR 876.1500, Product Code FCW, NTN)

Information on devices to which substantial equivalence is claimed:

510(K) Number	Trade or Proprietary or Model Name	Manufacturer
1 K082813	1. LED Light Source L9000	1. Stryker Endoscopy
2 K103813	2. LED Light Source SOPRO 281	2 SOPRO.
3 K121724	3 5160 ENDOLIGHT light Source	3 Richard Wolf Medical Instruments Corporation Inc..
4 K093792	4 LLS-050 LED light Source	4 Sunoptic Technologies

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Introduction:

Device Trade Name: NOVAPROBE LED Light Source (LEUKOS 175)

Common Name: Light source, Fiber Optic, Routine

Classification Name: Endoscope and accessories

Regulation Number: 21 CER 876.1500

Product Code: FCW, NTN

Device Description:

The NOVAPROBE LED LEUKOS 175 is specifically designed to provide the cold light intensity required for modern day Endoscopic procedures. The LED light provides the color temp of 6500 deg K also known as white light. The white light offers unmatched quality for the single chip, three chip and HD cameras. The LED light intensity is controlled digitally. Using LED nullifies any skin burning problems that may occur due to the use of arc lamps. The NovaProbe LED Light source assures that the light passing through the fiber optic cable is a cold light.

Intended Use:

The NovaProbe Inc. LED Light is used to illuminate the site of the surgery during minimally invasive surgical procedures in Arthroscopy (orthopedic surgery), Laparoscopy (general and gynecological surgery) and Endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the source through an optical cable and a scope.

Comparison of Technological Characteristics:

The technology of the NOVAPROBE LED LEUKOS 175 Light Source System is similar to the referenced predicate devices of LED Light Sources as they utilize the similar components as shown below.

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DEVICE COMPARISONS:

Device	510K Number	Intended Use	Lamp	Color Temperature
NOVAPROBE INC. LED LEUKOS 175	K131226	Cold Light Sources are Designed to supply light for endoscopic and diagnostic procedures	LED	6500K
Stryker Endoscopy LED Light Source L9000	K082813	Cold Light Sources are Designed to supply light for endoscopic and diagnostic procedures	LED	6500K
SOPRO LED Light Source SOPRO 281	K103813	Cold Light Sources are Designed to supply light for endoscopic and diagnostic procedures	LED	6000K
Richard Wolf Medical Instruments Corporation Inc.. 5160 ENDOLIGHT light Source	K121724	Cold Light Sources are Designed to supply light for endoscopic and diagnostic procedures	LED	6000K
Sunoptic Technologie LLS-050 LED light Source	K093792	Cold Light Sources are Designed to supply light for endoscopic and diagnostic procedures	LED	6000K

Device	510K Number	Bio compatibility	Used with	Light source Safety
NOVAPROBE INC. LED LEUKOS 175	K131226	N/A	Fiber-optic light cable, Rigid and Flexible Endoscope	Light Source output identical to LED light source K121724 and K082813
Stryker Endoscopy LED Light Source L9000	K082813	N/A	Fiber-optic light cable, Rigid and Flexible Endoscope	Light Source Safety demonstrated in 510k submission
SOPRO LED Light Source SOPRO 281	K103813	N/A	Fiber-optic light cable, Rigid and Flexible Endoscope	Light Source Safety demonstrated in 510k submission
Richard Wolf Medical Instruments	K121724	N/A	Fiber-optic light cable, Rigid and	Light Source Safety demonstrated in 510k

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Corporation Inc.. 5160 ENDOLIGHT light Source			Flexible Endoscope	submission
Sunoptic Technologies LLS-050 LED light Source	K093792	N/A	Fiber-optic light cable, Rigid and Flexible Endoscope	Light Source Safety demonstrated in 510k submission

Sterilization:

This system is a non-sterile system. The Light Source is to be cleaned with a soft cloth moistened with surface disinfectant, alcohol or spirit as defined in instruction manual.

Rational for Substantial Equivalence:

The NovaProbe Inc. LED LEUKOS 175 Light Source is substantially equivalent to Stryker Endoscopy LED light Source L9000 (K0828813), SOPRO LED light source 281(K103813), Richard Wolf ENDOLIGHT light source (K121724) and Sunoptic Technologies LLS-050 LED(K093792) light Source due to the fact that they all utilize similar components and technology as the NovaProbe Inc. LED LEUKOS 175 Light Source for the same approved intended uses. Further, the NovaProbe Inc. LED LEUKOS 175 Light Source introduces no new patient risks or concerns.

The NovaProbe Inc. **LED LEUKOS 175** Light Sources were non-clinically tested to determine the safety and efficacy under the indications for use and meet aforementioned safety standards, same as the predicate devices.

Performance Data:

Design verification testing demonstrates that the devices function as intended, and the Performance did not raise any new issues of safety and effectiveness, and that formal user training is not required.

No applicable mandatory performance standards or special controls exists for this device.

Clinical Data:

No clinical data was required to confirm safety and effectiveness.

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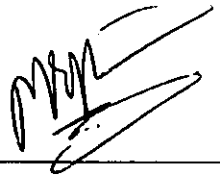
Conclusion:

Testing has shown that the NovaProbe Inc. LED LUEKOS 175 Light Source performs to its specifications, operates as intended, is safe and effective, and is substantially equivalent to legally marketed devices.

Contact: **Date:**



27 June 2014

Manish Ingle
President
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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 24, 2014

NovaProbe Incorporated
Mr. Manish Ingle
President
2333 West Main Street, Suite 210
Lansdale, Pennsylvania 19446

Re: K131226
Trade/Device Name: NovaProbe LED Light Source (LEUKOS 175)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FCW
Dated: June 18, 2014
Received: June 24, 2014

Dear Mr. Ingle:

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" (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 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,

David Krause -S

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)*
K131226

Device Name
NovaProbe LED Light Source (LEUKOS 175)

Indications for Use *(Describe)*

The NovaProbe Inc. LED Light is used to illuminate the site of the surgery during minimally invasive surgical procedures in Arthroscopy (orthopedic surgery), Laparoscopy (general and gynecological surgery) and Endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the source through an optical cable and a scope.

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)*

Neil R Ogden -S
2014.07.23 16:48:01 -04'00'

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