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

September 11, 2015

Peregrine Surgical Ltd.
c/o Mr. Ryan O'Leary
Product Development
51 Britain Dr.
New Britain, PA 18901

Re: K151604
Trade Name: Peregrine 23 ga and 25 ga Adjustable Chandelier Illuminator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: MPA
Dated: June 5, 2015
Received: June 15, 2015

Dear Mr. O'Leary:

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,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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)*

K151604

Device Name

23ga and 25ga Adjustable Chandelier Illuminator

Indications for Use *(Describe)*

Adjustable Chandelier Illuminator family of ophthalmic illuminators is for wide angle illumination during ophthalmic surgery.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5. 510(k) SUMMARY

510(k) SUMMARY for 23ga and 25ga Adjustable Chandelier Illuminator

1. Submitter Information:

Peregrine Surgical, Ltd.
51 Britain Drive
New Britain, PA 18901

Contact Person: Ryan O'Leary
Telephone Number: (215) 348-0456
Fax Number: (215) 348-5526

Date Prepared: 05 June 2015

2. Device Name:

Proprietary Name: 23ga and 25ga Adjustable Chandelier Illuminator
Classification Name: Endoilluminator
CFR Number: 876.1500
Device Class: II
Product Code: MPA

1. Predicate Device:

Table 5.1 Predicate Devices

Predicate Device Name	510(k)	Product Code	Company Name
Peregrine Tapered Diffusion Probe	K980025	MPA	Peregrine Surgical, Ltd.
23 Gauge (ga) Curved Illuminating Laser Probe	K122997	HQB, HQF, MPA	Peregrine Surgical, Ltd.

4. Description of Device:

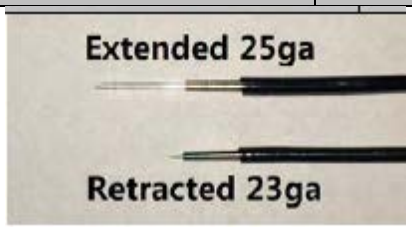
The 23ga and 25ga Adjustable Chandelier Illuminators are made to work with the Bausch and Lomb surgical system and Bausch and Lomb Valved ESA (Entry Site Alignment) systems (K012435). These devices are to be manufactured with distally located "Infusion Cannulas" that adequately secure themselves within 23ga and 25ga Bausch and Lomb Valved ESA Systems. The 23ga and 25ga Adjustable Chandelier Illuminators consist of a PMMA (Polymethylm-ethacrylate with Flourinated Polymer Cladding) acrylic fiber (for light transmission), white acetal handle assembly with finger slide for adjustability, PTFE (Polytetrafluor-oethylene) jacket (for fiber) and Stellaris style light connector to fit into the Bausch and Lomb Stellaris PC Vision Enhancement System (K133486).

The 23ga and 25ga Adjustable Chandelier Illuminators are to be provided sterile to the user, is a single-use device and is packaged in double Tyvek-to-poly pouches to facilitate introduction to the sterile environment. These probes provide illumination for eye surgery.

5. Indications for Use:
Adjustable Chandelier Illuminator family of ophthalmic illuminators is for wide angle illumination during ophthalmic surgery.

6. Substantial Equivalence:
Technological Characteristics -

Table 5.2 Technological Characteristics

Feature	Proposed Device Adjustable Chandelier Illuminator		Predicate Device Peregrine Tapered Diffusion Probe	Predicate Device 23 Ga Curved Illuminating Laser Probe
	23 Ga	25 Ga		
	 Note: The above photo reflects the chandlier in both the extended and retracted state. This portion of both gauges is identical except for the stainless infusion cannula which is slightly smaller on the 25ga version.			
510(k)	To be assigned		K980025	K122997
Product Code	MPA		MPA	HGB, MPA, HQF
Indications for Use	Adjustable Chandelier Illuminator family of ophthalmic illuminators is for wide angle illumination during ophthalmic surgery.		For wide angle illumination of the posterior segment during ophthalmic surgery.	For photocoagulation and illumination during ophthalmic surgery. This device delivers illumination as well as laser energy to target tissue, causing coagulation. Spot size can be varied by altering the distance between the tissue and probe tip.
Laser Connection	No laser connecter		No laser connecter	Ni/Cu Stainless Alloy Connector
Handpiece Construction	Acetal handpiece		Acetal handpiece	Acetal handpiece

Optical fiber	No laser fiber		No Laser Fiber	Glass-Silica core - .006" (150 microns)
Jacket Material	PTFE (Polytetrafluoroethylene)	PTFE (Polytetrafluoroethylene)	Polyethylene	Acrylated Olefin
Jacket Color	Black Green	Black Blue	Black	Orange
Inner Diameter (ID)	Black PTFE Jacket 0.022" Green PTFE Jacket 0.052"	Black PTFE Jacket 0.022" Blue PTFE Jacket 0.052"	0.046"	0.040"
Outer Diameter (OD)	Black PTFE Jacket 0.046" Green PTFE Jacket 0.084"	Black PTFE Jacket 0.046" Blue PTFE Jacket 0.084"	0.062"	0.070"
Length	91"	91"	82"	101"
Weight	0.4198 oz.	0.4198 oz.	0.3704 oz	0.9524 oz.
Gauge size	23 ga	25 ga	20 ga	23 ga
Illumination Fiber – OD	0.015"	0.0150"	0.030"	0.015"
Illumination Fiber Material	PMMA (Polymethylmethylacrylate with Fluorinated Polymer Cladding)	PMMA Polymethymethylacrylate with Fluorinated Polymer Cladding)	PMMA (Polymethylmethylacrylate with Fluorinated Polymer Cladding)	PMMA (Polymethylmethylacrylate with Fluorinated Polymer Cladding)
Stretch Capacity-OD*	Not stretched	Not stretched	Not stretched	0.0095"
Illumination Connector	Acetal with Stainless Tube	Acetal with Stainless Tube	Aluminum	Acetal with Stainless Tube
Light Output	3.7 lumen	3.7 lumen	7 lumen	3.4 lumen
Tip Angulation	Tapered	Tapered	Tapered	Straight
Needle Material	304 stainless (infusion cannula) – OD .025"	304 Stainless (infusion cannula) – OD .021"	304 stainless	304 stainless

The 23ga and 25ga Adjustable Chandelier Illuminators only transmit light energy, they do not control the intensity of the light output – this is controlled by the operating system to which it is attached. This is also true for both predicate devices.

The light connector for the 23ga and 25ga Adjustable Chandelier Illuminators is the same light connector utilized in the 23ga Curved Illumination Laser Probe (K122997) and is designed to fit into the light sources of the Bausch and Lomb Stellaris PC Vision Enhancement System (K133486).

The materials used to fabricate the acrylic fiber, handpiece and illumination connector used in the 23ga and 25ga Adjustable Chandelier Illuminators are identical to that of the 23ga Curved Illuminating Laser Probe as it was approved in K122997 on June 26, 2013 in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

The fiber used in the proposed device and both predicates is the exact same formulation (Polymethylmethacrylate (PMMA) with Flourinated Polymer Cladding) and is produced by the same supplier. The diameters of the fibers used in the 23ga and 25ga Adjustable Chandelier Illuminators and the 23ga Curved Illuminating Laser Probe are the same while the fiber used in the Tapered Diffusion is slightly bigger but still provides the same function.

The tapered fiber tip of the 23ga and 25ga Adjustable Chandelier Illuminators and the Tapered Diffusion Probe are manufactured in the same way and perform the same function.

4. Non-Clinical Performance Data

To evaluate the performance of the Adjustable Chandelier Illuminator, the following tests were conducted:

Test	Test Method
Sterility	ISO 11135-1
Shelf-life	ASTM F1980
Biocompatibility	ISO 10993-01
Light Output	Internal Test Method(ITP04-20)
Light Field	Internal Test Method (ITP04-30)
Thermal Inspection	Internal Test Method (ITP04-40)
Bond Strength	Internal Test Method (ITP03-75)
Cannula & Fiber Inspection	Internal Test Method (ITP52-00)

Biocompatibility and sterility testing has been conducted on the 25ga Adjustable Chandelier Illuminators as a "worst case device" and a family representative. All results were acceptable resulting in fully biocompatible device. The 23ga and 25ga Adjustable Chandelier Illuminators are made of the same materials as the predicate devices, Tapered Diffusion Probe (K980025) and 23ga Curved Illumination Laser Probe (K122997). The performance of the 23ga and 25ga Adjustable Chandelier Illuminators satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence.

5. Clinical Performance Data

No data from human clinical studies has been included to support the substantial equivalence of the 23ga and 25ga Adjustable Chandelier Illuminator.

6. Conclusion Regarding Substantial Equivalence

The 23ga and 25ga Adjustable Chandelier Illuminators are intended to provide illumination for eye surgery. The 23ga and 25g Adjustable Chandelier Illuminators have the same intended use, incorporate the same fundamental technology, and have similar indications for use as the predicate devices, Peregrine Tapered Diffusion Probe cleared under premarket notification K980025 and the 23ga Curved Illumination Laser Probe

cleared under K122997. Physically, the 23ga and 25ga Adjustable Chandelier Illuminators share characteristics with both predicate devices. The Tapered Diffusion Probe (K980025) was chosen as the primary predicate because the fiber is tapered in the exact same manner as the Chandelier and produces a very similar light output pattern. The 23ga Curved Illuminating Laser Probe (K122997) was chosen as a secondary predicate because it uses the same connector and connects to the same light source as the Chandelier. Test data to verify the performance of the 23ga and 25ga Adjustable Chandelier Illuminators has been provided including sterility, shelf-life, biocompatibility and functionality. The results of this testing, combined with the design and intended use comparison with the predicate devices, support substantial equivalence.