September 3, 2024

Peregrine Surgical, LLC
Melissa DeHass
QA/QC/RA Manager
51 Britain Drive
New Britain, Pennsylvania 18901

Re: K233653
Trade/Device Name: Midfield Light Pipe, 23ga (3269.M06-00); Midfield Light Pipe, 25ga (3269.M05-00); Midfield Light Pipe, 27ga (3269.M04-00)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: MPA

Dear Melissa DeHass:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 8, 2024. Specifically, FDA is updating the SE Letter to change the Sponsor's name from Peregrine Surgical Inc to Peregrine Surgical LLC as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elvin Ng, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices at Elvin.Ng@fda.hhs.gov.

Sincerely,

Alexander Beylin -S 2024.09.03 14:18:00 -04'00'

for Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

August 8, 2024

Peregrine Surgical Inc.
Melissa Dehass
QA/QC/RA Manager
51 Britain Drive
New Britain, Pennsylvania 18901

Re: K233653
Trade/Device Name: Midfield Light Pipe, 23ga (3269.M06-00); Midfield Light Pipe, 25ga (3269.M05-00); Midfield Light Pipe, 27ga (3269.M04-00)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: MPA
Dated: June 17, 2024
Received: June 17, 2024

Dear Melissa Dehass:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn).

Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alexander Beylin -S 2024.08.05 14:24:57 -04'00'

for Elvin Ng
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233653

Device Name

Midfield Light Pipe, 23ga (3269.M06-00);
Midfield Light Pipe, 25ga (3269.M05-00);
Midfield Light Pipe, 27ga (3269.M04-00)

Indications for Use *(Describe)*

The Midfield Light Pipe is a disposable microsurgical instrument used to conduct a field of light to the posterior segment of the eye in order to visualize the internal structures of the eyes 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Peregrine Surgical LLC
51 Britain Dr.
New Britain, PA 18901

1.2 Official Correspondent

Melissa DeHass
2380 Admire Springs Drive
Dover, PA 17315
Telephone: (717) 476-0702
Email: melissa@peregrine-surgical.com

1.3 Date of Preparation

June 17, 2024

2. NAME OF THE DEVICE

2.1 Trade/Proprietary Name

Midfield Light Pipe, 23GA (Reference No. 3269.M04-00)
Midfield Light Pipe, 25GA (Reference No. 3269.M05-00)
Midfield Light Pipe, 27GA (Reference No. 3269.M06-00)

2.2 Common/Usual Name

Endoilluminator

2.3 Classification Information

Classification Name:	Endoscope and accessories
Classification Regulation:	21 CFR 876.1500
Class:	2
Product Code:	MPA – Endoilluminator
Panel:	Ophthalmic

3. PREDICATE AND REFERENCE DEVICES

Device Name	510(k)	Device Manufacturer	Predicate or Reference	Regulation Number
23GA and 25GA Peregrine Chandelier Illuminators	K151604	Peregrine Surgical, LLC	Predicate	876.1500
Peregrine Diffusion Light Pipe	K950529	Peregrine Surgical, LLC	Reference	886.1945
EVA NEXUS Surgical System	K213467	D.O.R.C Dutch Ophthalmic Research Center (International)B.V.	Reference	886.4670

4. DESCRIPTION OF THE DEVICE

The Midfield Light Pipe will be offered in a 23 gauge (GA), 25GA and 27GA size. Each device consists of an ABS handpiece, 304 stainless steel illumination connector, LDPE EVA jacket material, PMMA illumination fiber, 304 stainless steel needle and a PMMA scleral depressor. The Midfield Light Pipe is an external communicating device, in contact with tissue/bone/dentin for a limited duration (<24 hours). The device will be identical to the existing Peregrine 23GA and 25GA Chandelier Illuminator (K151604) , except the illumination fiber used in the Midfield will have a higher numerical aperture (NA). The higher NA of the fiber will allow for a wider light field for improved visibility for the surgeon, without compromising illumination intensity ("brightness").

Peregrine will also provide a scleral depressor for use with the Midfield Light Pipe. Transcleral illumination makes use of the scleral depressor for examination of the vitreous base by manipulating and indenting the sclera while illuminating through the sclera. The scleral depressor is only intended to contact the outer surface of the eye (sclera) for a limited duration (≤24 hours).

The Midfield Light Pipes are comprised of common materials used in ophthalmic devices. The light pipe is mechanical and contains no electrical components. The Midfield Light Pipes 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.

5. INDICATION FOR USE

The Midfield Light Pipe is a disposable microsurgical instrument used to conduct a field of light to the posterior segment of the eye in order to visualize the internal structures of the eyes during ophthalmic surgery.

6. COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The Midfield Light Pipe is intended for use as an endoillumination light guide. The Midfield Light Pipe has an equivalent intended use as the predicate device, Peregrine 23GA and 25GA Chandelier Illuminator (K151604).

7. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

The Midfield Light Pipe is substantially equivalent to the predicate device regarding its similar intended use, function, design, materials, packaging and sterility.

The acrylic fiber utilized in the Midfield Light Pipes is comprised of the same materials, manufactured in the same manner and supplied by the same manufacturer as the fiber used in the predicate and reference devices. The only difference is the numerical aperture (NA). The Midfield Light Pipes utilize an illumination fiber with a higher numerical aperture (NA). This difference in NA is due to a difference in the formulation of the materials used in the fibers. No new materials are used, they are just used in different proportions. The higher NA of the fiber will allow for a wider light field for improved visibility for the surgeon, without compromising illumination intensity ("brightness").

The Midfield Light Pipe is packaged with a scleral depressor which serves as a protective cap.

Design verification and validation testing was conducted at t=0 and after accelerated aging to t=2 years to confirm that these changes do not raise issues of safety or effectiveness.

8. PERFORMANCE TESTING

These 510(k) notifications provide performance data to establish the substantial equivalence of the Midfield Light Pipe to the predicate device.

- Functionality
  - Light output
  - Needle strength
  - Phototoxicity (ISO 15004/ISO 15752)
- Sterilization (ISO 11607-1)
- Shelf-life (ASTM F1980)
- Packaging (ASTM D4169)
- Biocompatibility

Component	Material	Contact Type	Contact Duration	Assessment	Standard
Light Fiber	PMMA	Tissue/bone/dentin	Limited (≤24 hours)	Cytotoxicity	ISO 10993-5
				Irritation	ISO 10993-10
Shaft	304 Stainless Steel	Tissue/bone/dentin	Limited (≤24 hours)	Sensitization	ISO 10993-10
Adhesive	Loctite 4011	Tissue/bone/dentin	Limited (≤24 hours)	Subacute Toxicity	ISO 10993-11
				Material-Mediated Pyrogenicity	ISO 10993-11
Scleral Depressor	PMMA	Surface - Mucosal membrane	Limited (≤24 hours)	Cytotoxicity	ISO 10993-5
				Irritation	ISO 10993-10
				Sensitization	ISO 10993-10

Data from human clinical studies is not required to support the substantial equivalence of the Midfield Light Pipe.

9. CONCLUSIONS

The Midfield Light Pipes are intended to provide illumination for eye surgery. The Midfield Light Pipes have the same intended use, incorporate the same fundamental technology, and have similar indications for use as the predicate device, 23GA and 25GA Peregrine Chandelier Illuminator (K151604) and the reference device, Peregrine Diffusion Light Pipe (K950529). Physically, the Midfield Light Pipes share characteristics with both predicate and reference devices.

The EVA NEXUS Surgical System (K213467) was also selected as a reference device as it represents an operating system for which the Midfield Light Pipes are intended for use with. The Midfield Light Pipes, which are intended for use with the EVA NEXUS Surgical System, utilize the same biocompatible materials as the light pipes utilized with the EVA NEXUS Ophthalmic Surgical System (cleared under K213467). In addition, the EVA NEXUS Ophthalmic Surgical System and associated light pipes utilize a scleral depressor.

The information presented in this 510(k) submission demonstrates that the Midfield Light Pipe is substantially equivalent to the predicate device, Peregrine 23GA and 25GA Chandelier Illuminator (K151604).