DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 13, 2016

Anodyne Surgical
Ms. Valerie Anderson
Director Quality Assurance and Regulatory Affairs
804 Corporate Centre Drive
O' Fallon, Missouri 63368

Re: K160710
Trade/Device Name: Oasis Lacrimal Intubation Set with Retrieval Device
Regulation Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Unclassified
Product Code: OKS
Dated: March 14, 2016
Received: March 15, 2016

Dear Ms. Anderson:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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, and 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,

Kesia Alexander

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)*
Not known

Device Name

Oasis Lacrimal Intubation Set with Retrieval Device

Indications for Use *(Describe)*

The Oasis Medical Lacrimal Intubation Set is intended for use for nasolacrimal intubation in patients 12 months of age and older. Indications for nasolacrimal intubation performed with the Oasis Medical Lacrimal Intubation device are:

- Canalicular pathologies (e.g., congenital or acquired stenosis, lacerations)
- During dacryocystorhinostomy
- Congenital lacrimal duct obstruction

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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510(K) Submission

Oasis Lacrimal Intubation Set with Retrieval Device

510(K) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

Applicant's Name and Address:	Anodyne 804 Corporate Centre Drive O'Fallon, MO 63368
Contact Person:	Valerie Anderson Director Quality and Regulatory Affairs (T) 636-447-1010 (F) 636-447-1786
Date Prepared:	May 10, 2016
Device Trade Name:	Oasis Lacrimal Intubation Set with Retrieval Device
Common Name:	Lacrimal Intubation Set with Retrieval Device
Regulation Number:	Unclassified
Regulation Name:	Unclassified
Regulatory Class:	Unclassified
Product Code:	OKS
FDA Panel:	Ophthalmic
Predicate Device:	**Sold separately** - FCI, Crawford Bicanaliculus Intubation (Unclassified - K121142 - Product Code OKS) **and** Crawford Hook (Class 1 - 510(K) Exempt - Product Code HNQ – Reg. Number 886.4350)

PSI / EYE-KO, Inc. dba ANODYNE SURGICAL

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Device Description Summary:

The Oasis Lacrimal Intubation Set with Retrieval Device (Model 6004) is a sterile (via gamma sterilization-VDmax method-25kGy), single-use, hand held, and ophthalmic surgical device. The device consists of a twelve inch medical grade silicone tube that is secured at each end to two 4 ½", 23 gauge stainless steel, olive-tipped probes along with a 3" plastic handled retriever with a stainless steel hook.

The Oasis Lacrimal Intubation Set with Retrieval Device is used by a physician for nasolacrimal intubation. The insertion and removal for the Oasis Lacrimal Intubation Set with Retrieval Device is equivalent to the insertion and removal of the predicate device as evident in the IFU for each device. For insertion, each punctum should be dilated and the lacrimal system should be probed to open any blockages by using a standard lacrimal probe.

The first probe of the Lacrimal Intubation Set is passed through the upper punctum and across the upper canaliculus and then oriented down through the lacrimal system into the nose approximately 4cm.

Proper positioning of the probe can be confirmed by achieving metal-to-metal contact with the retrieval instrument inserted through the nostril. The probe end should be located lateral to the inferior turbinate in the inferior meatus of the nose. The retrieval instrument can be used to engage the probe at its olive tip and pull the probe out of the nose.

The second probe is passed down the inferior canaliculus and out

of the nose in a similar fashion.

The two exposed probes are cut from the silicone tube and removed. The ends of the silicone tube are tied to each other and securely knotted. The silicone tubes may be further secured by a tiny suture. Tuck the knotted silicone tubes up into the nose.

For removal, the silicone tube is located in the eye between the upper and lower puncta and pulling the tube upward. The silicone tube is then cut and pulled out completely from the ducts.

The knot used to tie the silicone tubes together is too big to pass through the canaliculus and the silicone tubes must be removed through the nose. In older patients it may be possible to expel the knot by having the patient blow their nose. In small children, location of the knot and silicone tube removal may need to be performed under general anesthesia.

Duration of intubation (patient contact of the silicone tube portion) is 24 hours to 30 days.

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Indications for Use: The Oasis Medical Lacrimal Intubation Set with Retrieval Device is intended for use for nasolacrimal intubation in patients 12 months of age and older. Indications for nasolacrimal intubation performed with the Oasis Medical Lacrimal Intubation device are:

- Canalicular pathologies (e.g., congenital or acquired stenosis, lacerations)
- During dacryocystorhinostomy
- Congenital lacrimal duct obstruction

The Indications for Use statement for the Oasis Medical Lacrimal Intubation Set with Retrieval Device is equivalent to the predicate device.

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Summary of Technological characteristics:

The Oasis Lacrimal Intubation with Retrieval Device is equivalent to the predicate device in terms of:

Oasis Lacrimal Intubation Design – probes and silicone

Mode of Action – intubation of the lacrimal ducts enabling drainage of tears by capillarity

Instructions for Use – insertion and removal

Oasis Lacrimal Intubation Materials – Stainless steel and silicone

Differences include:

Retrieval Device Design - The predicate hook is reusable whereas the Oasis Medical Lacrimal Intubation Set Retrieval Device is single-use and disposable (plastic handle). The reusable predicate hook is more substantial (stainless steel handle) for multiple uses. Slightly angled, ergonomic hook on the Oasis Medical Lacrimal Intubation Set Retrieval Device.

Retrieval Device Sterility - The predicate device hook is not provided sterile whereas the Oasis Medical Lacrimal Intubation Set with Retrieval Device is provided sterile.

Mode of Sterilization for Oasis Lacrimal Intubation - The predicate intubation device is EtO sterilized whereas the Oasis Medical Lacrimal Intubation Set with Retrieval Device is gamma sterilized via VDmax method (25kGy).

The device differences do not affect the Oasis Medical Lacrimal Intubation Set with Retrieval Device in terms of relevant functionality and safety.

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Biocompatibility: The biocompatibility evaluation for the Oasis Lacrimal Intubation with Retrieval Device included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Test results concluded this device did not elicit an adverse reaction during the above testing. The silicone tubing is considered the tissue contacting portion. The duration of contact is 24 hours to 30 days. In consideration of the Oasis Lacrimal Intubation with Retrieval Device manufacturing process, no novel impurities are introduced or added to the silicone and therefore the silicone material biocompatibility profile exceeds USP Class VI.

Summary of Non-clinical tests: The subject device performed equivalently to the predicate device in a series of bench tests which included an assessment of dimensional attributes and device durability via strength testing by means of applying a known pull force on the device junctions. It was concluded in this side-by-side comparison, the subject device and the predicate device have similar safety, effectiveness, and performance profiles because their overall design and strength are equivalent.

Substantial Equivalence Basis: The conclusions performed by independent laboratories and internal comparative bench testing provide objective evidence to substantiate the Oasis Lacrimal Intubation Set with Retrieval Device is as safe and effective as the predicate device that is currently marketed for the same intended use.