DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 18, 2017

Kaneka Pharma America LLC
% Izumi Maruo
Senior Consultant
MIC International
4-1-17 Hongo
Bunkyo-ku, Tokyo 113-0033, Japan

Re: K170247
Trade/Device Name: Lacriflow CL
Regulatory Class: Unclassified
Regulatory Name: Unclassified
Product Code: OKS
Dated: March 21, 2017
Received: March 22, 2017

Dear Izumi Maruo:

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,

Denise L. Hampton -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)*
K170247

Device Name
Lacriflow CL

Indications for Use *(Describe)*
The Lacriflow CL is indicated in treatments of epiphora in patients 12 months and older, in cases of:
- Canalicular pathologies (stenosis, obstruction, lacerations),
- During Dacryocystorhinostomy (conventional or laser),
- Congenital nasolacrimal 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.

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

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510(k) Summary

a. Owner/Company name, address

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b. Contact

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d. Date prepared

January 23, 2017

e. Name of device

Trade Name:	LACRIFLOW CL
Common Name:	Lacrimal stent
Classification Name:	Lacrimal Stents and Intubation Sets
Classification Regulation:	Unclassified
Product Code:	OKS

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f. Predicate devices

The LACRIFLOW CL is substantially equivalent to the following legally marketed device:

510(k):	K120886
Trade name:	LACRIFLOW
Product code:	OKS

g. Description of the device

The LACRIFLOW CL is intended for the treatment of epiphora due to conditions including the obstructions of lacrimal punctum, lacrimal canaliculus, or nasolacrimal duct. The LACRIFLOW CL consists of the Lacrimal duct tube and the Bougie. The Lacrimal duct tube is intended to be inserted and placed inside the lacrimal canaliculus or other sites to dilate the lacrimal duct, and the Bougie is intended to be used for the insertion of the Lacrimal duct tube and removed after insertion of Lacrimal duct tube. Lacrimal duct is dilated by insertion of the Lacrimal duct tube into the obstructed site.

h. Indications for Use

Indications for Use

The LACRIFLOW CL is indicated in treatments of epiphora in-patients 12 months and older, in cases of:
- Canalicular pathologies (stenosis, obstruction, lacerations),
- During Dacryocystorhinostomy (conventional or laser),
- Congenital nasolacrimal duct obstruction.

i. Statement of substantial equivalence

The LACRIFLOW CL was modified from the LACRIFLOW (K120886).

The Indications for Use of the LACRIFLOW CL is unchanged from the LACRIFLOW (K120886).

The LACRIFLOW CL contains the following modifications as compared to the LACRIFLOW (K120886);

- Elimination of stainless steel rings on both sides of the tube part
- Change in the shape of the tips of the lacrimal duct tube
- No openings on both ends of the lacrimal duct tube
- Change in the hydrophilic coating area
- The LACRIFLOW CL does not contain the “Mini” model

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Following comparison table provides technological characteristic between the subject and the predicate device;

Table 1. Comparison table between LACRIFLOW CL and the LACRIFLOW (K120886).

	SUBJECT DEVICE	PREDICATE DEVICE
	LACRIFLOW CL	LACRIFLOW (K120886)
Indications for Use	Same as the predicate	The LACRIFLOW is indicated in treatments of epiphora in patients 12 months and older, in cases of: -Canalicular pathologies (stenosis, obstruction, lacerations), -During Dacryocystorhinostomy (conventional or laser), -Congenital nasolacrimal duct obstruction.
Prescription use	Yes	Yes
Product Code	Same as the predicate	OKS
Tube Shape	Same as the predicate	Two tubes are connected by a rod part
Tip Shape	Pointed and no opening	Rounded and opening in both ends
Hydrophilic coating	Surface of the device except the tip part is coated	Entire surface of the device is coated
Size of the Tube		
- Length	Standard type: 105 mm Short type: 90 mm	Standard type: 105 mm Short type: 90 mm Mini type: 50 mm
-Outer Diameter	Same as the predicate	Tube part: 1.0 mm Rod part: 0.7 mm
Tensile Strength of the Tube	Same as the predicate	14.2 N (Average of 9 samples)
Insertion Method	Same as the predicate	The LACRIFLOW consists of the tube and the Bougie, and thus the Bougie is used for insertion.
Insertion Assist Parts	Same as the predicate	The Bougie
-Length	Same as the predicate	55 mm
-Outer Diameter	Same as the predicate	0.5 mm
-Tip Shape	Same as the predicate	Straight, helically grooved
-Tip Diameter	Same as the predicate	The same as the outer diameter
-Material	Same as the predicate	Stainless steel
Sterilization	Same as the predicate	Yes (Ethylene Oxide)

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Single-Use Only	Same as the predicate	Yes

The modification from the LACRIFLOW (K120886) includes material change. However, this change is caused by elimination of stainless steel ring and the LACRIFLOW (K120886) contains all materials used for the LACRIFLOW CL. Therefore, this modification does not alter the fundamental scientific technology of the device.

A risk analysis was conducted to assess the impact of the modifications on the subject device in accordance with our design control and ISO 14971. The design verification tests completed as follows:

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Table 2. Summary of design verification tests

Modification	Performance test
Elimination of stainless steel rings on both sides of the tube parts	Penetration test of the tip with the Bougie was performed.
Change in the shape of the tips of the lacrimal duct tube	Simulated insertion test was performed.
	Bending test for the tip was performed.
Change in the hydrophilic coating area	Inserting load was measured.
	Visual inspection regarding extraneous matter, abnormality which prevents use, coating droplet was performed.

In accordance with design control requirements in 21 CFR 820.30, the subject device met all verification tests listed above.

We determined that following modifications would not cause harm;

- The LACRIFLOW CL does not contain the "Mini" model
- No openings on both ends of the lacrimal duct tube

In conclusion, the LACRIFLOW CL is substantially equivalent to the LACRIFLOW (K120886).

a. Conclusion

The LACRIFLOW CL has the identical indications for use to the LACRIFLOW (K120886). The results of design verification tests based on the risk analysis demonstrate that the LACRIFLOW CL is substantially equivalent to the predicate devices.