510(k) Summary

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d. Date prepared
March 23, 2012

e. Name of device
Trade Name: LACRIFLOW
Common Name: Lacrimal stent
Classification Name: Lacrimal Stents and Intubation Sets
Classification Regulation: Unclassified
Product Code: OKS
f. Predicate devices
The LACRIFAST is substantially equivalent to the following legally marketed devices:

- 510(k): K991238
  Trade name: FCI CRAWFORD PROBE INTUBATION SETS
  Product code: OKS

- 510(k): K041869
  Trade name: SELF RETAINING BICANALICULUS INTUBATION SET
  Product code: OKS

g. Description of the device
The LACRIFLOW is intended for the treatment of epiphora due to conditions including the obstructions of lacrimal punctum, lacrimal canaliculus, or nasolacrimal duct. The LACRIFLOW 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 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
Following table is comparison between the LACRIFLOW and the predicates.

The Indications for Use of the LACRIFLOW is similar to that of the FCI CRAWFORD PROBE INTUBATION SETS (K991238). The elastic tube is inserted and placed inside the lacrimal drainage system in the application of the LACRIFLOW and the predicates, and thus the fundamental technology of the LACRIFLOW and the predicate is same.
<table>
<thead>
<tr>
<th>Indications for Use</th>
<th>LACRIFLOW</th>
<th>FCI CRAWFORD PROBE INTUBATION SETS (K991238)</th>
<th>SELF RETAINING BICANALICULUS INTUBATION SET (K041869)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The LACRIFLOW is indicated in treatments of epiphora in patients 12 months and older, in cases of:</td>
<td>BICANALICULAR INTUBATION SETS are indicated in treatments of epiphora in infants or adults, particularly in cases of:</td>
<td>Bicanalicular intubation is indicated in treatments of epiphora in adults (not to be used in infants), particularly in cases of:</td>
<td></td>
</tr>
<tr>
<td>- Canalicul pathologies (stenosis, obstruction, lacerations), - During Dacryocystorhinostomy (conventional or laser), - Congenital nasolacrimal duct obstruction.</td>
<td>- Canalicul pathologies (stenosis, obstruction, lacerations), - Dacryocystorhinostomy (conventional or laser), - Imperforation of the nasolacrimal duct in the infant.</td>
<td>- Meatic pathologies (meatic atresia) - Canalicul pathologies (canalicul stricture).</td>
<td></td>
</tr>
<tr>
<td>Tube Material</td>
<td>Polyurethane resin</td>
<td>Silicone</td>
<td>Silicone</td>
</tr>
<tr>
<td>Tube Shape</td>
<td>Two tubes are connected by a rod part</td>
<td>One tube</td>
<td>Two tubes are connected by a rod part</td>
</tr>
<tr>
<td>Size of the Tube</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Length</td>
<td>Standard type: 105 mm</td>
<td>Mini: 309.7 mm</td>
<td>S1-1290u: 25 mm</td>
</tr>
<tr>
<td></td>
<td>Short type: 90 mm</td>
<td>Maxi: 311.15 mm</td>
<td>S1-1291u: 30 mm</td>
</tr>
<tr>
<td></td>
<td>Mini type: 50 mm</td>
<td></td>
<td>S1-1292u: 35 mm</td>
</tr>
<tr>
<td>- Outer Diameter</td>
<td>Tube part: 1.0 mm</td>
<td>0.64 mm</td>
<td>0.64 mm</td>
</tr>
<tr>
<td></td>
<td>Rod part: 0.7 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tensile Strength of the Tube</td>
<td>14.2 N (Average of 9 samples)</td>
<td>3.56 N (Average of 3 samples)</td>
<td>1.98N (Average of 3 samples)</td>
</tr>
<tr>
<td>Insertion Method</td>
<td>The LACRIFLOW consists of the tube and the Bougie, and thus the Bougie is used for insertion.</td>
<td>BICANALICULAR INTUBATION SETS are composed of a tube connected to a steel guide at each end, and thus the steel guide is used for insertion.</td>
<td>The tube has flexible silicone anchor-shaped heads, and thus a forceps is used for insertion.</td>
</tr>
<tr>
<td>Insertion Assist Parts</td>
<td>The Bougie</td>
<td>The steel guides at both ends</td>
<td>NA (assisted by a forceps)</td>
</tr>
<tr>
<td>- Length</td>
<td>55 mm</td>
<td>Mini: 108 mm</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maxi: 115 mm</td>
<td></td>
</tr>
<tr>
<td>- Outer Diameter</td>
<td>0.5 mm</td>
<td>0.38 mm</td>
<td>NA</td>
</tr>
<tr>
<td>- Tip Shape</td>
<td>Straight, helically grooved</td>
<td>Rounded olive shape</td>
<td>NA</td>
</tr>
<tr>
<td>- Tip Diameter</td>
<td>The same as the outer</td>
<td>Mini: 0.75 mm</td>
<td>NA</td>
</tr>
</tbody>
</table>
As shown in the comparison table, the indications for use of the LACRIFLOW is similar to the FCI CRAWFORD PROBE INTUBATION SETS (K991238). In addition, as described above, the fundamental technology that the elastic tube is inserted and placed inside the lacrimal drainage system of the LACRIFLOW and the predicate is same. In the comparison table, there are some differences in characteristics between the LACRIFLOW and the predicates including the FCI CRAWFORD PROBE INTUBATION SETS (K991238) and the SELF RETAINING BICANALICULUS INTUBATION SET (K041869). Regarding the LACRIFLOW and the FCI CRAWFORD PROBE INTUBATION SETS (K991238), the tube shape and tube length are different because of difference of final step before the implantation. The FCI CRAWFORD PROBE INTUBATION SETS (K991238) needs to be tied both end, however, the LACRIFLOW does not need that step because the tube part is thicker than the lacrimal canaliculus. Regarding the LACRIFLOW and the SELF RETAINING BICANALICULUS INTUBATION SET (K041869), the tube length is different because the SELF RETAINING BICANALICULUS INTUBATION SET (K041869) is intended to be implanted in lacrimal canaliculus, not in nasoalclimal duct. In addition, the material of the Tube and insertion method including insertion assist part of the LACRIFLOW are different from the predicates. Therefore, performance testing, sterilization validation, biocompatibility testing, and risk analysis were performed in order to evaluate safety and effectiveness of the LACRIFLOW. In conclusion, those testing and analysis demonstrated that the LACRIFLOW did not raise any new safety or effectiveness concerns.

j. Risk Analysis
The LACRIFLOW was evaluated in accordance with ISO14971:2007. The risk management of the device was deemed satisfactory.

k. Bench Testing
The following bench tests were performed to ensure the safety and effectiveness of the Lacriflow and the conformance to in-house standards, and compare the characteristics with the predicate.

- Tensile Strength of the Lacrimal duct tube
  The tensile strength of the Lacrimal duct tube met acceptable minimum force until breakage when tested according to in-house standard.

- Stiffness of the Bougie
  The stiffness of the Bougie met acceptance criteria when tested according to in-house standard.
Result of all performance tests showed that the LACRIFLOW was compliant with in-house standards and the test result did not raise any new safety and effectiveness concern.

I. **Biocompatibility Testing**
In order to evaluate biocompatibility for the LACRIFLOW, we performed following biocompatibility tests;

- Cytotoxicity
- Irritation
- Sensitization
- Acute Systemic Toxicity
- 4-week and 13-week Systemic Toxicity
- Implantation (2-week and 9-week)
- Genotoxicity
- Hemolysis
- Pyrogen test
- LAL test

In the biocompatibility testing reports, no biocompatibility concern was raised.

m. **Conclusion**
The LACRIFLOW has the similar intended use to the FCI CRAWFORD PROBE INTUBATION SETS (K991238). The elastic tube is inserted and placed inside the lacrimal canaliculus in the application of the LACRIFLOW and the predicates, and thus the fundamental technology of the LACRIFLOW and the predicate is same. Although the LACRIFLOW has some different characteristics from the predicates including the FCI CRAWFORD PROBE INTUBATION SETS (K991238) and the SELF RETAINING BICANALICULUS INTUBATION SET (K041869), the LACRIFLOW did not raise any new safety or effectiveness concerns as the results of performance testing, sterilization validation, biocompatibility testing and risk analysis. Based on such testing and analysis, we concluded that the LACRIFLOW is substantially equivalent to the predicate devices.
Dear Dr. Kanai:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFices/ucml15809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

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
Indications for Use

510(k) Number (If known):  K120886

Device Name:  LACRIFLOW

Indications for Use
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- Canalicular pathologies (stenosis, obstruction, lacerations),
- During Dacryocystorhinostomy (conventional or laser),
- Congenital nasolacrimal duct obstruction.

X
Prescription Use  ___  AND/OR  Over-the-Counter Use  ___
(Per 21 CFR 801 Subpart D)  (21 CFR 801 Subpart C)

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
Division of Neurological and Physical Medicine Devices
510(k) Number  K120886