December 18, 2020

FCI (France Chirurgie Instrumentation) SAS
% Barbara S. Fant
President
Clinical Research Consultants, Inc.
3308 Jefferson Avenue, Upper Level
Cincinnati, OH 45220

Re: K201606
Trade/Device Name: LacriJet®
Regulatory Class: Unclassified
Product Code: OKS
Dated: November 13, 2020
Received: November 16, 2020

Dear Barbara S. Fant:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

J. Angelo Green, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201606

Device Name
LACRIJET®

Indications for Use *(Describe)*
LACRIJET® from 30 to 50 mm are indicated in the treatment of congenital lacrimal duct obstructions (stenosis of the valve of Hasner) in patients 12 months and older.

LACRIJET® with small size (15/20 mm) are indicated in the repair of canalicular lacerations.

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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K201606

510(k) Summary as required by 21 CFR§807.92(c)

510(k) Owner: France Chirurgie Instrumentation SAS (FCI S.A.S.)
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75015 Paris, France
Telephone: +33 1 53 98 98 98
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Contact Person: Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
3308 Jefferson Avenue
Upper Level
Cincinnati, OH 45220
Phone: (513) 961-8200
Facsimile: (513) 961-2858

Date: December 4, 2020

Trade Name: LacriJet®

Common name: Monocanalicular Lacrimal Stent

Classification Name: Lacrimal Stents and Intubation Sets

Product Code: OKS

Identification of a Legally Marketed Predicate Device

Primary Predicate Device: MASTERKA intubation, 510(k) Premarket Notification Number K113536, FDA Product Code OKS.

Secondary Predicate Device: Eagle Vision Monocanalicular Stent, 510(k) Premarket Notification Number K883233, FDA Product Code OKS.

Reference Device: Mini-Monoka, 510(k) Premarket Notification Number K911109, FDA Product Code OKS.

General Description

LacriJet® is a monocanalicular intubation device, with self-retaining punctal fixation for the treatment of monocanalicular lacerations and stenoses. The silicone stent acts as a conformer. The shape of the fixation head keeps the probe from migrating and from expulsing.

Indications for Use

LacriJet® from 30 to 50mm are indicated in the treatment of congenital lacrimal duct obstructions (stenosis of the valve of Hasner) in patients 12 months and older.

LacriJet® with small size (15/20mm) are indicated in the repair of canalicular lacerations.

Comparison of Technological Characteristics

LacriJet® is substantially equivalent to the MASTERKA predicate device as both devices have the same intended use and intubation method, with similar indications and contraindications for use statements. LacriJet® is also substantially equivalent to the Eagle Vision Monocanalicular Stent secondary predicate and the Mini-Monoka reference device as both devices have the same intended use and intubation method, and are indicated for repair of canalicular lacerations. The stent (implant part) of both the LacriJet® and MASTERKA primary predicate device are molded from the same medical grade silicone. The design of the fixation head that anchors the device in place is the same for both devices.

The primary difference between LacriJet® and the MASTERKA primary predicate is in the design of the delivery system. The LacriJet® is delivered via an injector hand piece designed to optimize insertion and delivery of the stent to reduce operating time in the intubation and guide removal phase of the procedure. The LacriJet® stent is preloaded in a metallic tube and is fully protected inside the metallic tube. Once the guide enclosing the stent is fully inserted, the safety ring is disengaged, allowing the piston to be pulled and slowly retract the guide, revealing the stent which remains in position in the patient's lacrimal system. The MASTERKA stent is pre-mounted on a metal introducer with a PEEK handle to facilitate insertion of the stent. The introducer is easily and completely removed once the intubation of the lacrimal passages has been completed.

LacriJet® is packaged in a PETG blister with Tyvek cover and sterilized by gamma radiation, while the MASTERKA predicate is packaged in a Tyvek sachet and sterilized by ethylene oxide. Both sterilization methods sterilize to an SAL of 10^{-6}. These differences in technological characteristics do not raise new concerns of safety or effectiveness.

Brief Summary of Non-Clinical Tests and Results

LacriJet® has been designed and tested to the applicable standards. All nonclinical test results met the established specifications for the device. In-process controls and final product quality controls, including finished product release testing and inspection, assure that LacriJet® is manufactured within specifications. The biocompatibility of the silicone raw material meets the required specifications, confirming that LacriJet® can be implanted for periods longer than 29 days. Gamma radiation specifications, package integrity studies, and stability studies were performed to the applicable standards, and the test results support the shelf-life and storage conditions for the device.

The results from non-clinical testing demonstrate LacriJet® meets the established specifications for the device and that the test results and established specifications are substantially equivalent to those of the MASTERKA primary predicate device.

Basis of Substantial Equivalence

LacriJet® is substantially equivalent to the MASTERKA primary predicate device with respect to the intended use as monocanalicular intubation device for the treatment of congenital lacrimal duct obstructions, basic design concept consisting of a stent body (tube) and fixation head, biocompatibility of the medical grade silicone raw materials used to manufacture the device which are manufactured by FCI SAS and distributed in the USA by FCI Ophthalmics, Inc. LacriJet® is substantially equivalent to the Eagle Vision MonoStent secondary predicate and Mini-Monoka reference devices with respect to the intended use as a monocanalicular intubation device for the repair of canalicular lacerations.