March 11, 2021

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

Re: K201892
Trade/Device Name: Ritleng®+ and Ritleng®+ PVP
Regulatory Class: Unclassified
Product Code: OKS
Dated: February 12, 2021
Received: February 16, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201892

Device Name
RITLENG®+
RITLENG®+ PVP

Indications for Use *(Describe)*

The RITLENG®+ products are indicated in the treatment of epiphora in patients of 12 months and older in cases of:
- Canalicular pathologies (stenoses, obstructions, lacerations),
- Congenital duct obstruction (Hasner valve stenosis),
- Dacryocystorhinostomy (conventional or laser).

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

510(k) Number: **K201892**

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
Facsimile: +33 1 53 98 98 99

Contact Person: Barbara S. Fant, Pharm.D.
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Phone: (513) 961-8200
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Date: March 4, 2021

Trade Name: RITLENG®+
RITLENG®+ PVP

Common name: Bicanalicular Lacrimal Stent

Classification Name: Lacrimal Stents and Intubation Sets

Product Code: OKS

Identification of a Legally Marketed Predicate Device

RITLENG®+ is substantially equivalent to the RITLENG® intubation marketed by FCI Ophthalmics, Inc., 510(k) Premarket Notification Number K955671, FDA Product Code OKS.

General Description

The RITLENG®+ is a self-retaining nasal bicanalicular intubation for the lacrimal ducts. It consists of a silicone tube with two larger diameter portions, connected at each extremity with a PEEK thread guide. Each thread guide has a wide diameter part and a narrow diameter part. The silicone tube may be coated with polyvinylpyrrolidone (PVP) to improve its wettability. The central body of the intubation displays a marking intended for the intubation placement between the lacrimal puncta.

Intended Use

The RITLENG®+ products are indicated in the treatment of epiphora in patients of 12 months and older in cases of:

- Canalicular pathologies (stenoses, obstructions, lacerations),
- Congenital duct obstruction (Hasner valve stenosis),
- Dacryocystorhinostomy (conventional or laser).

Comparison of Technological Characteristics

RITLENG®+ is substantially equivalent to the RITLENG® Intubation as both devices have the identical intended use and intubation method, with similar indications for use statements. The implant part of both devices is made from the identical medical grade silicone: and the silicone tube of both devices may be coated with polyvinylpyrrolidone (PVP) to improve its wettability. Both devices are packaged in a double Tyvek pouch and sterilized by Ethylene Oxide to a sterility level of SAL 10^{-6}.

The difference between the two devices is the addition of the two larger diameter portions of the silicone tube to the RITLENG®+ that create a self-retaining (autostable) feature when placed in the lacrimal ducts.

Based on this comparison, RITLENG®+ is substantially equivalent to the RITLENG® predicate device (K955671).

Brief Summary of Non-Clinical Tests and Results

RITLENG®+ 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 RITLENG®+ is manufactured within specifications. The biocompatibility of the device is supported by cytotoxicity testing per ISO 10993-5, three sets of chemical characterization testing using different patient contacting device components per ISO 10993-18, and toxicological risk assessment based on these chemical characterization results. The biocompatibility of the subject device was also supported by biocompatibility information comparison of the materials used in the subject device to the materials used in the cleared predicate. Ethylene oxide sterilization 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 RITLENG®+ meets the established specifications for the device and that the test results and established specifications are substantially equivalent to those of the RITLENG® predicate device.

Basis of Substantial Equivalence

RITLENG®+ is substantially equivalent to the RITLENG® predicate device with respect to the intended use as a bicanalicular intubation device for the treatment of congenital lacrimal duct obstructions, and the 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.