DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 3, 2016

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

Re: K161373
Trade/Device Name: Nunchaku
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OKS
Dated: September 23, 2016
Received: September 28, 2016

Dear Ms. 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. 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 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)*
K161373

Device Name
Nunchaku

Indications for Use *(Describe)*
The Nunchaku stents are intended for use for nasolacrimal intubation in patients 12 months and older. Indications for nasolacrimal intubation performed with the Nunchaku are:
- Canalicular pathologies (e.g., congenital or acquired stenosis, laceration)
- 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.

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

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510(k) Summary

510(k) Number: K161363

510(k) Owner: France Chirurgie Instrumentation SAS (FCI S.A.S.)
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Phone: (513) 961-8200
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Date: September 23, 2016

Trade Name: Nunchaku

Common name: Bicanaliculus Intubation

Classification Name: Lacrimal Stents and Intubation Sets

Product Code: OKS

Identification of a Legally Marketed Predicate Device

The Nunchaku is substantially equivalent to the Crawford Bicanaliculus Intubation marketed by FCI Ophthalmics, Inc., 510(k) Premarket Notification Number: K121142, FDA Product Code OKS; and the Nunchaku is also substantially equivalent to the Lacriflow marketed by Kaneka, 510(k) Premarket Notification Number: K120886, FDA Product Code OKS, and to the Self-Retaining Bicanaliculus Intubation Set II marketed by FCI Ophthalmics, Inc., 510(k) Premarket Notification Number: K130375, FDA Product Code OKS.

General Description

The Nunchaku is a bicanalicular intubation device for the treatment of epiphora in patients 12 months and older. The device consists of two lateral silicone tubes connected to a silicone body that is delivered pre-mounted on two guides. The guides facilitate insertion of the Nunchaku and are completely removed once insertion of the device is complete. The Nunchaku comes in two different model lengths (90 or 105 mm depending on length of tube required) and is provided as a sterilized product.

Intended Use

The Nunchaku stents are intended for use for nasolacrimal intubation in patients 12 months and older. Indications for nasolacrimal intubation performed with the Nunchaku are:

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

Comparison of Technological Characteristics

The Nunchaku, Crawford Bicanaliculus Intubation, and Self-Retaining Bicanaliculus Intubation Set II manufactured by FCI are identical, or nearly identical, in every respect except the Nunchaku is pre-mounted on two metal guides to facilitate insertion of the device. The Nunchaku (manufactured by FCI) and the Lacriflow (manufactured by Kaneka) are also identical, or nearly identical, in every respect including pre-mounting onto two metal guides, except that the Lacriflow is manufactured from a polyurethane material. All three devices have a stent body (tube) that is manufactured from nearly identical medical grade silicone (Nunchaku, Crawford Bicanaliculus Intubation, Self-Retaining Bicanaliculus Intubation Set II) or medical grade polyurethane material (Lacriflow). The Nunchaku, Crawford Bicanaliculus Intubation, and Self-Retaining Bicanaliculus Intubation Set II are manufactured using the same processes and gluing methods, are ethylene oxide sterilized, and provided in similar packaging. The stainless steel materials used in each device are medical grade with well characterized mechanical and biocompatibility properties. The Nunchaku and Crawford Bicanaliculus Intubation are used with a sizer that is packaged and sold separately by FCI S.A.S.. The Self-Retaining Bicanaliculus Intubation Set II uses the same sizer, which is pre-packaged with the Self-Retaining device along with a disposable dilator.

Brief Summary of Non-Clinical Tests and Results

The manufacturing process was validated, demonstrating the capacity of FCI S.A.S. and FCI SUD to manufacture the Nunchaku. Bench top testing was performed on samples before and after sterilization to validate the mechanical characteristics of the silicone tube. Testing included

an evaluation of guide detachment during insertion, the mechanical integrity of the device during guide insertion and removal, and tensile strength testing. All non-clinical test results met the established specifications for the device. Test results on the silicone material demonstrated that the silicone was of sufficient tensile strength to resist breakage and device pull-out.The biocompatibility of the raw materials was tested to the applicable ISO standards for cytotoxicity (MEM elution assay), irritation (intracutaneous reactivity in rabbits), sensitization (guinea pig maximation), systemic toxicity, muscular implantation,and to USP standards for endotoxins. The biocompatibility test results met the required specifications for all tests. The biocompatibility of the finished devices were also tested for Ethylene oxide sterilization validation studies, shipping and package integrity studies were performed according to the applicable standards; and, the test results support the shelf-life and storage conditions for the device.

From the testing, it can be concluded that the Nunchaku performs as intended and is constructed of biocompatible materials.

Basis of Substantial Equivalence

The Nunchaku is substantially equivalent to the Crawford Bicanaliculus Intubation and Self-Retaining Bicanaliculus Intubation Set II in material, intended use, basic design concept, sterilization methods, and biocompatibility. The Nunchaku is also substantially equivalent to the Lacriflow in intended use, design concept, and dimensions. The main difference is that the Nunchaku, Lacriflow, and Self-Retaining Bicanaliculus Intubation Set II devices are all pre-mounted onto metallic guides to facilitate insertion; whereas, the Crawford Bicanaliculus Intubation device has a flexible metallic guide affixed to each end of the silicone tube that is removed nasally after fixation of the device is confirmed as part of the stent placement procedure. The Nunchaku, Crawford Bicanaliculus Intubation, and Self-Retaining Bicanaliculus Intubation Set II are both manufactured by FCI S.A.S. and distributed in the U.S.A. by FCI Ophthalmics, Inc. The Lacriflow is manufactured by Kaneka Corporation in Japan and distributed in the U.S.A. by Kaneka Pharma America, LLC.