May 27, 2020

Raico LLC
Ravi Nallakrishnan
President
26 Plaza Dr
Westmont, IL 60559

Re: K192418
Trade/Device Name: Phacoemulsification Needle (Tip) & Irrigation Sleeve
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: April 16, 2020
Received: April 17, 2020

Dear Ravi Nallakrishnan:

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,

for Tieuvi Nguyen, Ph.D.
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)*
K192418

Device Name
Phacoemulsification Needle (Tip) and Irrigation Sleeve

Indications for Use *(Describe)*

The RAICO Phacoemulsification Tip is used to break up (emulsify) the nucleus of a cataractous lens and remove the remaining nuclear fragments.

The RAICO Irrigation Sleeve is intended to direct irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.

The RAICO Phacoemulsification Tip is intended for use in conjunction with the Irrigation Sleeve during ocular surgery.

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.

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510(k) SUMMARY K192418

This 510(k) summary has been prepared in accordance with 21 CFR 807.92.

1. Submitter

RAICO, LLC
26 Plaza Dr.
Westmont, IL 60559, USA
Establishment Registration : 3015528097

Contact Person:

Ravi Nallakrishnan
RAICO International, LLC
26 Plaza Dr.
Westmont, IL 60559, USA
Ravi@Raicousa.com
Phone: (630) 986-8032
Fax: (630) 986-0065

Date Prepared: April 8, 2020

2. Device

Device Subject to this 510(k):

Trade Name:	Phacoemulsification Needle (Tip) and Irrigation Sleeve
Common Name:	Phacoemulsification Needle & Irrigation Sleeve
Classification Name:	Phacofragmentation System (Product Code HQC; 21 CFR 886.4670)
Classification:	II

3. Predicate Devices

510(k) Number	Device
K121721	Laminar Flow Phacoemulsification Tip and Irrigation Sleeve (Primary Predicate)
K111882	Laminar Flow Phacoemulsification Tip

4. Device Description

Phacoemulsification is a common practice in modern cataract surgery in which the eye's internal lens is emulsified with an ultrasonic handpiece and aspirated from the eye. The ultrasonic handpiece is connected to, and powered by a phacoemulsification system, which is identified in 21 CFR 886.4670 as "an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract."

The primary device that is the subject of this 510(k) is a "Phacoemulsification Tip" (or "Phaco Tip") that is connected to the ultrasonic phacoemulsification handpiece. The Phacoemulsification Tip vibrates at an ultrasonic frequency, powered by the handpiece and surgical system, and thus emulsifies the cataract. The fragmented tissue is then be aspirated and removed through the lumen of the tip. During a surgical procedure, irrigation solution is used to irrigate the eye and this is passed with the help of an “Irrigation Sleeve”, a small molded component that is placed over the Phacoemulsification Tip.

The RAICO Phacoemulsification Tip is packaged with a RAICO Irrigation Sleeve. The RAICO Phacoemulsification Tip and RAICO Irrigation Sleeve are made of medical grade titanium and silicone, respectively.

In addition, test chamber and wrench accessories are included in the package and all of the devices and accessories will be sterilized, labeled and intended for single use only.

5. Indications for Use

The Indications for Use statement for the RAICO Phacoemulsification Tip and Irrigation Sleeve are identical to the predicate devices. The RAICO Phacoemulsification Tip is used to break up (emulsify) the nucleus of a cataractous lens and remove the remaining nuclear fragments.

The RAICO Irrigation Sleeve is intended to direct irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.

The RAICO Phacoemulsification Tip is intended for use in conjunction with the Irrigation Sleeve.

Both the subject and predicate devices have the same intended use.

6. Comparison of Technological Characteristics with the Predicate Devices

There are no technological characteristics, features or dimensional attributes of the RAICO Phacoemulsification Tips and Irrigation Sleeves that have not been previously cleared in predicate devices, as described in Tables 1 and 2.

Table 1: Comparison of the Technological Characteristics of the RAICO Phacoemulsification Tip and Predicate Devices

Features and Characteristics	**RAICO Phacoemulsification Tip**	**Predicate Laminar Flow Phaco Tip (K121721) Primary Predicate**	**Predicate Laminar Flow Phaco Tip (K111882)**
Intended Use	With an ultrasonic handpiece during phacoemulsification surgery	With an ultrasonic handpiece during phacoemulsification surgery	With an ultrasonic handpiece during phacoemulsification surgery
Description	The needle supplies ultrasonic movement at the tip to break up cataract material. The needle also supports an aspiration fluid path for removing cataract particles from the eye	The needle supplies ultrasonic movement at the tip to break up cataract material. The needle also supports an aspiration fluid path for removing cataract particles from the eye	The needle supplies ultrasonic movement at the tip to break up cataract material. The needle also supports an aspiration fluid path for removing cataract particles from the eye
Handpiece Compatibility	AMO Ultrasonic Handpieces	AMO Ultrasonic Handpieces	AMO Ultrasonic Handpieces
Patient Contact Material	Titanium, Medical Grade	Titanium, Medical Grade	Titanium, Medical Grade
Sterilization Method	Ethylene Oxide	Gamma Radiation	Gamma Radiation
Use	Single Use	Reusable	Single Use
Thread	Right-Handed	Right-Handed	Right-Handed
Tip Bevel Angle	Straight: 0-60 º Curved: 30-45º	Straight: 0-60° Curved: 30-45°	Straight: 0-60° Curved: 30-45°
Hub Design	Tapered with 5 lands	Tapered with 5 lands	Tapered with 5 lands
Tip Shape	Straight and Curved	Straight and Curved	Straight and Curved
Curve Range	0-24º	0-24°	0-24°

Table 2: Comparison of the RAICO Irrigation Sleeve and Predicate Device

Features and Characteristics	RAICO Irrigation Sleeve	Predicate Laminar Flow Irrigation Sleeve (K121721)
Intended Use	To provide irrigation during phacoemulsification surgery	To provide irrigation during phacoemulsification surgery
Description	The sleeve directs irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.	The sleeve directs irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.
Patient Contact Material	Silicone, Medical Grade	Silicone, Medical Grade
Sterilization Method	Ethylene Oxide	Gamma Radiation
Use	Single Use	Reusable
Colorant	Yellow 129	Light Blue (Gray 61-801220, Blue 121 and White 177 Gum, odorless, stable, insoluble) Orange (Red 042 and Yellow 185 Gum, odorless, stable, insoluble)
Flow Rate (cc/min)	≥ 40	≥ 40
Gauge Size	21G	21G
Length Range (inches)	1.0	1.0
Weight (grams/sleeve)	0.38	0.4
Durometer (units)	80 ± 5	80 ± 5

7. Performance Data

Functionality testing to compare the RAICO Phacoemulsification Tips and Irrigation Sleeves to the predicate phacoemulsification tips and irrigation sleeves was conducted. This testing included priming and tuning of phaco tips with handpiece and phaco machine, cutting properties including resonant frequency, ultrasonic stroke performance and velocity calculation, as well as irrigation performance, aspiration capability and material tensile strength.

The RAICO Phacoemulsification Tips and Irrigation Sleeves are provided sterile and are intended for single-use. These devices will be ethylene oxide sterilized using a cycle validated per AAMI/ISO standards.

Sterilization validation, stability (shelf-life) and packaging integrity have also been tested and, based on the results obtained, the RAICO Phacoemulsification Tip and Irrigation Sleeve are deemed to be substantially equivalent to the legally marketed predicate devices.

Biocompatibility evaluation of the RAICO Phacoemulsification Tips and Irrigation Sleeves was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995. These biocompatibility studies have shown the material used in these devices to be biocompatible and safe for use during surgery.

8. Conclusions

As described in this 510(k) Summary, the RAICO Phacoemulsification Tips and Irrigation Sleeves have been demonstrated to be substantially equivalent to the predicate devices for their intended use.