August 16, 2019

Johnson & Johnson Surgical Vision, Inc.
Larry Boucher
Regulatory Affairs Project Manager
1700 East Saint Andrew Place
Santa Ana, CA 92705

Re: K191933
Trade/Device Name: COMPACT INTUITIV™ System, COMPACT INTUITIV™ Wireless Remote Control, COMPACT INTUITIV™ Four-Button Foot Pedal, COMPACT INTUITIV™ Closed-Toe Foot Pedal
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: July 17, 2019
Received: July 19, 2019

Dear Larry Boucher:

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 Malvina B. Eydelman, M.D.
Director
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)*

Device Name
COMPACT INTUITIV™ System

Indications for Use *(Describe)*
The COMPACT INTUITIV™ System is an AC-powered device with a fragmenting needle for cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

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

The following 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92:

Applicant:	Johnson & Johnson Surgical Vision, Inc. 1700 East Saint Andrew Place Santa Ana, CA 92705 USA Phone: 408-723-5166 Fax: 408-273-5966
Contact Person:	Larry Boucher Project Manager, Regulatory Affairs lbouche1@its.jnj.com Phone: 714-247-8391 Fax: 714-566-3785
Date Prepared:	July 17, 2019
Trade Name of Device:	COMPACT INTUITIV™ System
Classification of Device:	21 CFR 886.4670 – Class II
Product Code	HQC
Predicate Device:	COMPACT INTUITIV™ System, 510(k) #: K133115
Performance Data:	The COMPACT INTUITIV™ System has undergone design verification and validation testing, including electromagnetic compatibility testing, to demonstrate compatibility with the proposed closed-toe foot pedal. In addition, software validation was performed on the proposed software version. All testing demonstrated that the closed-toe foot pedal met acceptance criteria. No animal or clinical studies were performed as there is no change to the indications for use or the fundamental scientific technology when compared to the predicate device.
Conclusion:	The closed-toe foot pedal is substantially equivalent to the currently cleared COMPACT INTUITIV™ Four Button Foot Pedal based on the completion of non-clinical bench testing, software validation, as well as similar principles of design, operation, and indications for use.

Device Description

The COMPACT INTUITIV™ System is a modular ophthalmic microsurgical system that is intended for use in anterior segment (cataract) surgery. The device is used to emulsify and extract a cataractous lens. The COMPACT INTUITIV™ is a mid-tier peristaltic system with a graphic-user that has updated technology and hardware to meet current electrical and material safety standards. The currently cleared COMPACT INTUITIV™ consists of the System Console, the Wireless Remote Control, the Open-Toe Foot Pedal, and the Single-Use Fluidics Pack, Model OPO80.

The closed-toe foot pedal is equivalent to the currently cleared open-toe foot pedal for use with the COMPACT INTUITIV™ system. The closed-toe foot pedal provides similar functionality as the open-toe foot pedal. Both open-toe and closed-toe foot pedals contain three-programmable switches, and the closed-toe device incorporates a programmable treadle. Both open and closed toe foot pedals provide tactile feedback to the user. The switches and treadle on the foot pedal can be programmed to access features on the COMPACT INTUITIV™ System Console based on the surgeon's preference.

Intended Use

The COMPACT INTUITIV™ System is an AC-powered device with a fragmenting needle for cataract surgery to disrupt a cataract with ultrasound and extract the cataract.

Substantial Equivalence

The subject COMPACT INTUITIV™ Closed-Toe Foot Pedal is substantially equivalent to the predicate COMPACT INTUITIV™ Open-Toe Foot Pedal which was cleared under premarket notification K113155 (cleared February 27, 2014), in terms of:

- Indications for use
- Intended use
- Fundamental technological characteristics

The COMPACT INTUITIV™ Closed-Toe Foot Pedal is identical to that cleared for use with the Sovereign Compact Phacoemulsification System (K111446, cleared December 21, 2011), the reference device.

Table 1 provides a comparison of the characteristics of the closed-toe foot pedal, the predicate device, and the reference device:

Table 1: Comparison of COMPACT INTUITIV™ system with Open- and Closed-Toe Foot Pedals and Sovereign Compact Phacoemulsification Device with Closed-Toe Foot Pedal

Attribute	Subject Device	Predicate Device	Reference Device
Device Description	COMPACT INTUITIV™ System with closed-toe foot pedal	COMPACT INTUITIV™ System with open-toe foot pedal	Sovereign Compact Phacoemulsification System with closed-toe foot pedal
510(k) Number	Not assigned	K113155	K111446
Regulation Number	886.4670	886.4670	866.4670
Regulation Name	Photofragmentation system	Photofragmentation system	Photofragmentation system
Regulatory Class	Class II	Class II	Class II
Product Code	HQC	HQC	HQC
Indications for Use	The COMPACT INTUITIV™ System is an AC-powered device with a fragmenting needle for cataract surgery to disrupt a cataract with ultrasound and extract the cataract	The COMPACT INTUITIV™ System is an AC-powered device with a fragmenting needle for cataract surgery to disrupt a cataract with ultrasound and extract the cataract.	The Sovereign Compact Phacoemulsification System is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.
Purpose of Foot Pedal	Determines the function delivered by the handpiece, which depends on the mode selected (diathermy, phacoemulsification, irrigation/aspiration, or vitrectomy)	Determines the function delivered by the handpiece, which depends on the mode selected (diathermy, phacoemulsification, irrigation/aspiration, or vitrectomy)	Determines the function delivered by the handpiece, which depends on the mode selected (diathermy, phacoemulsification, irrigation/aspiration, or vitrectomy)
Description	Single Linear	Single Linear	Single Linear
Size	9.82” W x 15.57” D x 4.88” H	9.82” W x 15.57” D x 4.88” H	9.82” W x 15.57” D x 4.88” H
User-Programmable Buttons	Three buttons (one each to the right and left, third above the foot) and treadle	Three (one each on the right and left, third to the right of the pedal)	Three buttons (one each to the right and left, third above the foot) and treadle
Connector Type	12-pin connector	12-pin connector	12-pin connector
Power Cord	Detachable	Detachable	Detachable
Power Cord Length	11.5 feet	12.0 feet	11.5 feet
System Type	Phacoemulsification System	Phacoemulsification System	Phacoemulsification System

The subject foot-pedal utilizes same functionality, performance, technology and intended use as the predicate foot pedal (K113155, COMPACT INTUITIV™ System).

Summary of Bench and Animal Performance Testing

The functionality of the closed-toe foot pedal was tested to determine the compatibility with the COMPACT INTUITIV™ System. Testing included connectivity of the foot pedal to the COMPACT INTUITIV™ System, foot pedal modes, functionality of the tactile feedback and the programmable switches. Functional bench Testing demonstrated that the closed-toe foot pedal met all acceptance criteria.

Software specific bench testing of the COMPACT INTUITIV™ System for a proposed software version which contains minor changes to accommodate use of the System with the closed-toe foot pedal, was conducted to demonstrate the System's ability to meet all intended design specifications related to the software design changes.

Electromagnetic compatibility (EMC) testing was performed in conformance with IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests and test results demonstrated that the closed-toe foot pedal when used with the COMPACT INTUITIV™ System met all requirements of the standard.

The results of the bench testing, EMC testing, and software validation demonstrates that the use of the closed-toe foot pedal with the COMPACT INTUITIV™ System is substantially equivalent to the currently cleared open-toe foot pedal.