March 12, 2021

Johnson & Johnson Surgical Vision, Inc.
Amanda Houston
Senior Regulatory Affairs Specialist
1700 East St. Andrew Place
Santa Ana, CA 92705

Re: K203060
Trade/Device Name: VERITAS™ Phacoemulsification Console, VERITAS™ Advanced Fluidics Pack and Advanced Infusion Pack
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: January 21, 2021
Received: January 22, 2021

Dear Amanda Houston:

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 LT Charles Chiang
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)*
K203060

Device Name
VERITAS(TM) Vision System

Indications for Use *(Describe)*
The VERITAS(TM) Vision System is a modular ophthalmic microsurgical system that facilitates anterior segment (i.e., cataract) ophthalmic surgery. The modular design allows the user to configure the system to meet their surgical requirements.

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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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)*
K203060

Device Name
VERITAS(TM) Advanced Infusion Pack or VERITAS(TM) Advanced Fluidics Pack

Indications for Use *(Describe)*
The VERITAS(TM) Advanced Infusion Pack or VERITAS(TM) Advanced Fluidics Pack contains the manifold (cassette) and Tubing Assembly and is intended to perform irrigation and aspiration during anterior segment cataract surgery. It is used with the VERITAS(TM) Vision System. The VERITAS(TM) Pack is sterilized using ethylene oxide and is designed for single use only.

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)

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

510(k) Summary: K203060

Sponsor/ Submitter:	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:	Amanda Houston Sr. Regulatory Affairs Specialist ahousto1@its.jnj.com 512-789-8317
Date Prepared:	March 12, 2021
Device Trade Names:	VERITAS™ Vision System VERITAS™ Advanced Infusion Pack and Advanced Fluidics Pack
Common Name:	Phacoemulsification System
Device Classification:	Class II
Regulation Number:	21 CFR 886.4670
Classification Name:	Phacofragmentation System
Product Code:	HQC
Primary Predicate Device: VERITAS™ Vision System	WhiteStar Signature Pro Phacoemulsification System, (K151636)
Secondary Predicate Device: VERITAS™ Packs	OPO73 Dual Pump Fluidics Pack (K160236)
Reference Predicate Devices: VERITAS™ Vision System	WhiteStar Signature Phacoemulsification System, (K111697, WhiteStar Handpiece) Sovereign Cataract Extraction System, (K981116, Ellips Handpiece) Bausch and Lomb Stellaris Elite Phacoemulsification System, (K162342)

Device Description

The VERITAS™ Vision System is a modular ophthalmic microsurgical system that is intended for use in anterior segment (cataract) ophthalmic surgery. The device uses ultrasonic energy via finely modulated pulses of energy, interrupted by brief cooling periods, to emulsify and extract a cataractous lens. This allows the system to achieve full ultrasound cutting efficiency while introducing less energy to the eye, which reduces risk of thermal damage. The VERITAS™ System performs phacoemulsification, diathermy, irrigation/aspiration, and vitrectomy functions, and is a peristaltic system with a graphic user interface that has updated technology and hardware to meet current electrical and material safety standards.

The intended use of the subject device is anterior segment ophthalmic surgery (i.e., cataract), which is the same as the primary and secondary predicate devices. The materials, energy source, operating mechanism, fundamental scientific technology, physical properties, duration, and type of contact, and intended use of the subject device are identical to those of the WHITESTAR SIGNATURE® Pro Phacoemulsification System and the OPO73 Dual Pump Fluidics Pack. The VERITAS™ Vision System is intended for use by trained ophthalmic surgeons and their support staff under the direction of the surgeon in adult patients with cataracts or adult patients undergoing anterior segment ophthalmic surgery (e.g., removal of the crystalline lens).

The VERITAS™ Vision System consists of components that are used to perform cataract surgery, which include the 1) System Console, 2) Wireless Remote Control, 3) Advanced Foot Pedal and 4) Single-Use Fluidics Pack or Single-Use Infusion Pack 5) Swivel Handpiece 6) Hardware 7) Software.

The functionality of the subject and primary predicate devices is the same, with the exception of the addition of Gas Forced Infusion (GFI) functionality to the subject device, which adds supplemental pressure to the existing gravitational forces within the irrigation line. The wireless remote control, foot pedal, and phacoemulsification handpiece are also updated versions of the accessories that are used with the primary predicate device.

Other modifications made for the subject device are:

- Redesigned exterior skin
- Slightly larger 19-inch touchscreen display
- Updated venting algorithm which can be configured by the user
- Continuous irrigation auto-off feature – irrigation will stop when the handpiece is removed from the eye
- Updated Mayo tray design for improved cleaning robustness
- Updated foot pedal
- Updated, smaller remote for easier use

Indications for Use

The VERITAS™ Vision System is a modular ophthalmic microsurgical system that facilitates anterior segment (i.e., cataract) ophthalmic surgery. The modular design allows the user to configure the system to meet their surgical requirements. The indications for use are identical to the primary predicate WHITESTAR SIGNATURE® PRO.

The VERITAS™ Advanced Infusion Pack or VERITAS™ Advanced Fluidics Pack contains the manifold (cassette) and Tubing Assembly and is intended to perform irrigation and aspiration during anterior segment cataract surgery. It is used with the VERITAS™ Vision System. The VERITAS™ Pack is sterilized using ethylene oxide and is designed for single use only.

Difference in Indications for Use from Secondary Predicate

The VERITAS™ Advanced Infusion Pack and VERITAS™ Advanced Fluidics Pack Indications for Use statement is essentially identical to the secondary predicate device, OPO73 Dual Pump Fluidics Packs. A minor revision has been made to include reference to both models of the VERITAS packs (Advanced Infusion Pack and Advanced Fluidics Pack) whereas the secondary predicate device had a single product reference included. In addition, product nomenclature was also revised.

Technological Characteristics of the Device

The main technological characteristics of the VERITAS™ Vision System include phacoemulsification, diathermy, irrigation and aspiration, and vitrectomy. These technological characteristics are the same as those in the legally marketed device, the WHITESTAR SIGNATURE® PRO Phacoemulsification System (K151636).

- The Phacoemulsification mode is used to break up (emulsify) the nucleus of a lens, allowing it to be aspirated from the eye through a small incision.
- The Diathermy (bipolar) mode is used to coagulate blood vessels during a surgical procedure and, in some cases, to coagulate the conjunctiva following a procedure.
- The Irrigation/Aspiration mode allows for controlled aspiration of cortical material from the eye, while maintaining intraocular stability by replacing aspirated material with a balanced salt solution. A peristaltic pump provides a predictable and stable aspiration rate. Irrigation is gravity-fed, and intraocular pressure can be regulated by adjusting the height of the balanced salt solution bottle.
- The Vitrectomy mode is used to cut and remove vitreous from the anterior segment of the eye during secondary intraocular lens implantation, following vitreous loss associated with trauma, or during primary cataract surgery.

These surgery modes are equivalent to the surgery modes of the primary predicate device, the WHITESTAR SIGNATURE Pro Phacoemulsification System.

Substantial Equivalence

The subject VERITAS™ Vision System is substantially equivalent to the primary WHITESTAR SIGNATURE® PRO Phacoemulsification System which was cleared under premarket notification K151636 (cleared October 29, 2015), in terms of:

- Indications for use
- Intended use
- Fundamental technological characteristics

In addition, the VERITAS™ Advanced Fluidics Pack and VERITAS™ Advanced Infusion Pack are substantially equivalent to the secondary predicate device, the OPO73 Dual Pump Fluidics Pack

cleared under K160236 (cleared April 27, 2016). The VERITAS™ Advanced Fluidics Pack is identical in functionality to the secondary predicate device; however, the Advanced Infusion Pack adds an infusion line that adds supplemental pressure to the irrigation system. This enhancement does not alter the overall functionality of the Advanced Infusion Pack.

The following reference devices listed in **Table 1** provide additional support for the substantial equivalence of the VERITAS™ Vision System:

Table 1: List of Reference Devices

Reference Devices	Reason for Reference	VERITAS™ Vision System
WhiteStar Signature Phacoemulsification System, (K111697, WhiteStar Handpiece)	The WhiteStar Signature Phacoemulsification System, which includes the WhiteStar Handpiece, was the primary predicate device for the WhiteStar Signature Pro Phacoemulsification System	The WhiteStar Handpiece is compatible with the VERITAS™ Vision System.
Sovereign Cataract Extraction System (K981116, Ellips Handpiece)	The Ellips handpiece was first cleared for use as part of the Sovereign Cataract Extraction System.	The Ellips handpiece was a component of the WhiteStar Signature Pro Phacoemulsification System, which is the primary predicate device for the VERITAS™ Vision System
Bausch and Lomb Stellaris Elite Phacoemulsification System, (K162342)	Gas Forced Infusion functionality	The VERITAS™ Vision System includes Gas Forced Infusion functionality to add supplemental pressure to the irrigation line

Table 2 provides a comparison of the VERITAS™ Vision System and the primary predicate device:

Table 2: Comparison of VERITAS™ Vision System with WHITESTAR SIGNATURE PRO Phacoemulsification System

Attributes	Predicate Device	Subject Device
	WHITESTAR SIGNATURE® PRO Phacoemulsification System	VERITAS™ Vision System
510(k)	K151636	K203060
Intended Use	Anterior Segment Ophthalmic Surgery	Same
Indications for Use	Modular ophthalmic microsurgical system that facilitates anterior segment (cataract) surgery. The modular design allows the users to configure the system to meet their surgical requirements.	Same

Attributes	Predicate Device WHITESTAR SIGNATURE® PRO Phacoemulsification System	Subject Device VERITAS™ Vision System
Target Population	Adult patients with cataracts or adult patients undergoing anterior segment ophthalmic surgery (e.g., removal of the crystalline lens).	Same
Intended User	Ophthalmologist and support staff operating under the direction of the surgeon.	Same
Energy Used	Ultrasonic energy	Same
Multifunction Wired/Wireless Foot Pedal	Yes	Same
Wireless remote control	Yes	Same
Surgical media center (optional)	Yes	Same
iPad Viewing Capability (optional)	Yes	Same
GFI Functionality	No	Yes
User interface: **Touchscreen graphical user interface (GUI)**	Yes	Same
Wireless remote control	Yes	Same
Multifunction Wired/Wireless Foot Pedal	Yes	Same
Accessories: **Tubing packs**	Yes	Same
Phaco handpieces, tips, and sleeves	Yes	Same
Pneumatic vitrectomy handpiece	Yes	Same
Irrigation/aspiration (I/A) handpiece	Yes	Same
Diathermy forceps, pencil, and cord	Yes	Same
Instrument sterilization tray	Yes	Same
Power cord	Yes	Same
Operator's Manual	Yes	Same
Software operating environment **-GUI host** **-Instrument host**	-Windows 7(embedded) -QNX 6.5 with SP1	Same
Programming Language	C++	Same

Attributes	Predicate Device WHITESTAR SIGNATURE® PRO Phacoemulsification System	Subject Device VERITAS™ Vision System
Operating Temperature Range	+10 to +40°C	Same
Maximum Humidity (RH or relative humidity)	95% RH non-condensing	Same
Microprocessor-based	Yes	Same
Programmable for Multiple Surgeons	Yes	Same
Electrical Power Specification	100-240VAC, 50/60 Hz	Same
Self-Diagnostic	Yes	Same
Real-Time Display	Yes	Same
U/S Pulse Mode	Yes	Same
Diathermy/Cautery	Yes	Same
Irrigation	Yes	Same
Aspiration Pump Type	Peristaltic and Venturi pump capabilities	Same
Vacuum Range (in mm mercury)	0-650 (peristaltic) 0-600 (Venturi)	Same
Anterior Vitrectomy	Yes	Same
Voice Confirmation	Yes	Same
Prime Mode	Yes	Same
Machine Width, Depth, Height Hie	24” W x 24” D x 54”H	24” W x 24” D x 62” H
Hardware (Modular Design): - System console, with active matrix color LCD display screen, Mayo stand/tray and programmable IV pole	Yes	Hardware (Modular Design): Same with 19" diagonal, active matrix TFT LCD display screen.
Foot Pedal		
Description	Programmable Foot Switch	Same
Purpose	Control and operation of programs and handpieces	Same
Actuation	Single Linear; Dual Linear	Same
User Programmable Buttons	Four	Same
Wired/Wireless	Yes	Same

Attributes	Predicate Device	Subject Device
	WHITESTAR SIGNATURE® PRO Phacoemulsification System	**VERITAS™ Vision System**
Battery Charging	Rechargeable	Same
Remote Control		
Purpose	System control and program selection	Same
Wired/Wireless	Wireless	Same
Number of Buttons	12	11
Battery Charging	Conductive Charge	None (User-replaceable AA batteries)
Handpiece		
Purpose	Emulsification and removal of lens	Same
Energy Source	Piezoelectric crystals	Same
Crystal Vibration Frequency	37.5-39.5kHz	38-40kHz
Re-sterilization Method	Compatible with conventional autoclave sterilization methods	Same
Swivel Proximal Handle	No	Yes
Description	WHITESTAR Phaco Handpiece, Ellips FX Phaco Handpiece	VERITAS™ Swivel Handpiece, Ellips FX Phaco Handpiece, WHITESTAR Phaco Handpiece
Luer Lock Attachment	No (Friction Fit)	Yes (for irrigation luer in Advanced Infusion and Advanced Fluidics Pack with Veritas Swivel Handpiece)
Smart Technology	No	Yes, EPROM to track number of primes for assessing device usage

Table 3 provides a comparison between the VERITAS™ Advanced Fluidics Pack, the VERITAS™ Advanced Infusion Pack, and the secondary predicate device.

Table 3: Substantial Equivalence Table: Comparison of Fluidics Packs Used for the VERITAS Vision System

Attributes	Predicate Device	Subject Device	Subject Device
	DUAL PUMP PACK MODEL OPO73	**VERITAS™ ADVANCED FLUIDICS PACK MODEL VRT-AF**	**VERITAS™ ADVANCED INFUSION PACK MODEL VRT-AI**
510(k)	K160236	K203060	K203060
Intended Use	Cataract Surgery (Anterior segment)	Same	Same

Attributes	Predicate Device	Subject Device	Subject Device
	DUAL PUMP PACK MODEL OPO73	VERITAS™ ADVANCED FLUIDICS PACK MODEL VRT-AF	VERITAS™ ADVANCED INFUSION PACK MODEL VRT-AI
Indications for use	Perform irrigation and aspiration during anterior segment cataract surgery	Same	Same
Size	5.0" L x 4.375" W x 2.2" H	Same	Same
Peristaltic Aspiration Support	Yes	Same	Same
Venturi Aspiration Support	Yes	Same	Same
Pack Loading	Single-Step	Same	Same
Usage	Single-Use	Same	Same
Packaging	Thermoform tray with Tyvek Lid	Same	Same
Tray Components	Housing Manifold with I/A Tubing Touchscreen cover Mayo tray stand cover Pouched test chamber	Same	Same
Function	Irrigation/Aspiration	Same	Same with Supplemental Pressure
Shelf Life	Three (3) years	Two (2) years	Two (2) years
Compatible Surgical System	VERITAS™ Vision System WhiteStar Signature Pro System	VERITAS™ Vision System	VERITAS™ Vision System

Summary of Performance Testing

VERITAS™ Console, VERITAS™ Foot Pedal, VERITAS Wireless Remote Control, and VERITAS Swivel Handpiece

The VERITAS™ Vision System has undergone preliminary design verification and validation testing to address regulatory requirements, including electromechanical safety testing (IEC 60601 testing), electromagnetic compatibility testing, and software validation, and is in compliance with the applicable requirements. The subject device passed the acceptance criteria and was found to perform as safely and effectively as the primary predicate device during the following modes of anterior segment ophthalmic surgery: phacoemulsification, irrigation/aspiration, diathermy, and vitrectomy. Therefore, the subject device, including the VERITAS™ console, VERITAS™ Foot Pedal VERITAS™ Wireless Remote Control and VERITAS™ Swivel Handpiece, has similar safety, effectiveness, and performance profiles as the primary predicate device.

VERITAS™ Advanced Fluidics Pack and VERITAS™ Advanced Infusion Pack

The VERITAS™ Advanced Fluidics Pack and VERITAS™ Advanced Infusion Pack have undergone design verification and validation testing. The test results demonstrate that the Advanced Fluidics Pack and Advanced Infusion Pack perform as safely and as effectively as the secondary predicate device, the OPO73 Dual Pump Fluidics Pack. During performance testing, all anterior segment ophthalmic surgery modes that require the Advanced Fluidics Pack and Advanced Infusion Pack functionality, including irrigation/aspiration and gas-forced infusion were conducted; all tests passed and all acceptance criteria were met.

Components of the VERITAS™ Advanced Fluidics Pack and VERITAS™ Advanced Infusion Pack have indirect contact with the patient by providing a fluid path for sterile Balanced Salt Solution (BSS) to enter the eye during surgery. A sterilization equivalency assessment was conducted for the adoption of the Veritas packs to the current process employed for the OPO73 Dual Pump Packs and determined that the Veritas packs may be considered similar or equivalent to the OPO73 packs for validation purposes. Verification and validation testing, including sterilization validation (using ISO 11135:2014 and ISO 11137:2014, Sterilization of Health-Care Products – Ethylene Oxide) and biocompatibility testing (using ISO 10993:2018, Biological Evaluation of Medical Devices), was completed and all acceptance criteria were met, demonstrating that the VERITAS™ Advanced Fluidics Pack and VERITAS™ Advanced Infusion Pack have a similar safety, effectiveness and performance profile as the secondary predicate device.

Risk assessment has been performed in accordance with ISO 14971:2017. Formative and summative human factor studies identified no new risks associated with the VERITAS™ Vision System. 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 primary and secondary predicate devices.

Conclusion:

The results of the bench testing, EMC testing, and software validation demonstrates that the VERITAS™ Vision System and VERITAS™ Advanced Infusion Pack and Advanced Fluidics Pack have met all required acceptance criteria. The VERITAS™ Vision System is substantially equivalent to the currently cleared WhiteStar Signature Pro Phacoemulsification System (K151636) based on completion of non-clinical bench testing, software validation, as well as similar principles of design, operation, and indications for use. The VERITAS™ Advanced Fluidics Pack Model VRT-AF and VERITAS™ Advanced Infusion Pack Model VRT-AI are substantially equivalent to the currently cleared Dual Pump Pack Model OPO73 (K160236) based on completion of non-clinical bench testing, software validation, as well as similar principles of design, operation, and indications for use.