June 14, 2022

D.O.R.C. Dutch Ophthalmic Research Center (International)
Linda Leeuwen
Regulatory Affairs Officer
B.V. Scheijdelveweg 2
Zuidland, Zuid Holland 3214 VN
Netherlands

Re: K213467
Trade/Device Name: EVA NEXUS Ophthalmic Surgical System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE, HQF, FMF
Dated: April 28, 2022
Received: May 6, 2022

Dear Linda Leeuwen:

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,

Anjana Jain, PhD
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)*
K213467

Device Name
EVA NEXUS™ Ophthalmic Surgical System

Indications for Use *(Describe)*
The EVA NEXUS™ Ophthalmic Surgical System is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery, including subretinal microinjection of gases or aqueous fluids.

In addition, the optional laser is indicated for the following:

Condition	Treatment
Diabetic Retinopathy	
• Proliferative Diabetic Retinopathy	Panretinal Photocoagulation
• Clinically Significant Macular Edema	Focal or Grid Laser
Retinal Tear and Detachments	Laser Retinopathy
Lattice Degeneration	Retinal Photocoagulation
Sub-retinal (choroidal) Neovascularization	Focal Laser
Retinal Vascular Occlusion	
• Neovascularization secondary to Branch or Central retinal vein occlusion	Scatter Laser Photocoagulation
• Chronic macular edema secondary to Branch or Central retinal vein occlusion	Focal or Grid Laser
Glaucoma	
• Primary Open-angle	Trabeculoplasty
• Closed Angle	Iridotomy or Iridoplasty

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

This summary is in accordance with 21 CFR 807.92.

1. Submitter

The submitter of the 510(k) is:

D.O.R.C. Dutch Ophthalmic Research Center (International) B.V.
Scheijdelveweg 2
3214 VN Zuidland
The Netherlands

Contact person:

Linda Van Leeuwen, Regulatory Affairs Officer
Tel: +31 181 45 8080
Fax: +31 181 458090
Mail: l.vanleeuwen@dorcglobal.com

Date Prepared: June 14, 2022

2. Device

Device Subject to this 510(k):

Trade Name: EVA NEXUS™ Ophthalmic Surgical System
Common Name: Phacoemulsification/Vitrectomy System
Classification Name: Class II

The following regulations are applicable for this 510(k):

- 21 CFR 886.4670 Phacofragmentation System (Product Code: HQC)
- 21 CFR 886.4150 Vitreous Aspirating and Cutting Device (Product Code: HQE)
- 21 CFR 886.4390 Ophthalmic Laser (Product Code: HQF)
- 21 CFR 886.5860 Piston Syringe (Product Code FMF)

3. Predicate Device(s)

510(k) number	Device	Predicate for
K190875	EVA Ophthalmic Surgical System (DORC)	EVA NEXUS™ Ophthalmic Surgical System
K142877	8267 and 8268.series vitrectomes	9268.series vitrectomes
K142877	8110.series tubing	9110.series tubing
K024061	7525.series stepped laser probes	7227.series directional laser probes
K203264	MicroDose™ Injector (MedOne)	1364.DD - 1 cc syringe holder for micro injection
K200325	Orbit Subretinal Delivery System (Orbit SDS)	1364.DD - 1 cc syringe holder for micro injection

4. Indications for Use

The EVA NEXUS™ Ophthalmic Surgical System is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery, including subretinal microinjection of gases or aqueous fluids.

In addition, the optional laser is indicated for the following:

Condition	Treatment
Diabetic Retinopathy	
• Proliferative Diabetic Retinopathy	• Panretinal Photocoagulation
• Clinically Significant Macular Edema	• Focal or Grid Laser
Retinal Tear and Detachments	Laser Retinopathy
Lattice Degeneration	Retinal Photocoagulation
Sub-retinal (choroidal) Neovascularization	Focal Laser
Retinal Vascular Occlusion	
• Neovascularization secondary to Brand or Central retinal vein occlusion	• Scatter Laser Photocoagulation
• Chronic macular edema secondary to Branch or Central retinal vein occlusion	• Focal or Grid Laser
Glaucoma	
• Primary Open-angle	• Trabeculoplasty
• Closed Angle	• Iridotomy or Iridoplasty

5. Device Features

The purpose of this 510(k) is to obtain clearance for improvements to the cleared device. These changes include:

- **Infusion pole:** The adjustable infusion pole has been replaced with a bottle holder at fixed height.
- **Second infusion/irrigation port:** A second infusion/irrigation port is introduced so that the surgeon can connect and prime vitrectome and phaco-handpiece at the start of the surgery to ensure smooth transition between anterior and posterior procedures. It has been ensured in EVA NEXUS software that the two infusion/irrigation ports cannot be used simultaneously.

- **Smart IOP:** A setting called Smart IOP is introduced, that allows the surgeon to use an automatic infusion/irrigation based on a preset desired Intra Ocular Pressure (IOP). EVA NEXUS uses predefined instruments characteristics and the set aspiration to determine the required infusion/irrigation pressure.

- **Microinjection capability:** Currently the Viscous Fluid Injection is suitable for injection of approximately 10 ml of fluid. The Microinjection capability uses exactly the same functionality, but is suitable for injection of volumes as small as 50 µl. The injection is controlled by means of the footswitch which allows the surgeon to hold the delivery device in a stable position without the need to push a syringe plunger manually. This capability is intended for subretinal

microinjection of gases or aqueous fluids.
In order to use a surgical system to aid with the injection an adaptor kit to the surgical system should be used. For this purpose, 1364.DD is available: a 1 cc syringe holder for micro injection.

- **Phaco board**: Is now a digitally controlled board instead of the previous board being based on analog technology.
- **Increased cutter speed:** The cutter speed of the vitrectomes is increased to maximally 10,000 cuts per minute, based on a regular vitrectome. For the TDC (Two Dimensional Cutter) vitrectomes that cut both on the forward and backward motion, the cutting speed is effectively doubled to maximally 20,000 cuts per minute. At this moment 9268.series TDC vitrectomes are introduced to support the maximum drive of 10,000 cycles per minute (which equals 20,000 cuts per minute).

- **Video overlay device:** The possibility to connect a video-overlay device is introduced, that allows the surgeon to show EVA NEXUS settings on the surgical video.

- **Software:** To support these changes the EVA NEXUS software was upgraded as well as anomaly/bug fixes.

- **Accessory Changes**:
  - **Surgical packs** (combinations of accessories): New configurations are added specifically for use on EVA NEXUS
  - **Change of 1364.DD**: 1 cc syringe holder for micro injection. An updated version of 1364.DD that was included in K142877 with documentation. The syringe supplier changed, as well as the product name.
  - **Tubing sets**: Tubing sets specifically for EVA NEXUS have been developed to accommodate for the two infusion/irrigation ports.
  - **Addition of new vitrectomes:** To support the increased cutting speed and to update look and feel.
  - **Changed phaco needles and sleeves:** The design of the phaco needles was optimized to improve holdability of lens fragments; sleeves were re-designed to maximize irrigation flow and optimize sleeve positioning.
  - **Addition of directional laser probes:** Apart from the existing directional laser probes, currently marketed OUS by DORC, DORC has introduced directional laserprobes in 27 gauge size.

A comparison between EVA NEXUS under evaluation and the predicate EVA system can be found in Table 5.

Table 5 Comparison of EVA NEXUS (under evaluation) and the EVA system.

Item compared	sub category	K213467 EVA NEXUS (Subject Device) (9000.ANTxx/COMyy)	K190875 Predicate device EVA (8000.ANTxx/COMyy)	Equivalence (same / similar / different)
Technical Characteristics				
General				
General functional overview	Design	The EVA NEXUS console provides the following functions: - Phaco-emulsification - Vitrectomy - Diathermy - Irrigation / Aspiration - Illumination - Fluid/Air exchange - Viscous fluid control (injection, extraction, Micro Injection) - Laser - Visualization (Digital overlay)	The EVA console provides the following functions: - Phaco-emulsification - Vitrectomy - Diathermy - Irrigation / Aspiration - Illumination - Fluid/Air exchange - Viscous fluid control (injection, extraction) - Laser - Proportional scissor	Different
General Product composition	Design	Console, footswitch, power cable, accessories for different purposes including phacoemulsification, vitrectomy, illumination, Inspiration/Aspiration, diathermy, and laser. Procedure packs.	Console, footswitch, power cable, accessories for different purposes including phacoemulsification, vitrectomy, illumination, Inspiration/Aspiration, diathermy, and laser. Procedure packs.	Similar
	Dimensions	70x185x60 cm	72x167x60 cm	Similar
	Weight	128 kg	142 kg	Similar
User Interfaces				
User Interfaces	Principle of operation	The user selects settings for the various functions on the Graphical User Interface by the touch screen, or by the remote control. The user starts, stops, and regulates the various functions with the foot switch.	The user selects settings for the various functions on the Graphical User Interface by the touch screen, or by the remote control. The user starts, stops, and regulates the various functions with the foot switch.	Same
User Interfaces	Console screen	Glass Color display Touchscreen (19 inch) with programmable Graphical User Interface	Glass Color display Touchscreen (19 inch) with programmable Graphical User Interface	Same
User Interfaces	Multi-function footswitch	Multi-function footswitch with a dual-linear pedal and programmable function buttons to control all functions including laser. Wired and Wireless connection to the console. Battery-operated with wall charger and back-up power/connection cable.	Multi-function footswitch with a dual-linear pedal and programmable function buttons to control all functions including laser. Wired and Wireless connection to the console. Battery-operated with wall charger and back-up power/connection cable.	Same
User Interfaces	Remote	a remote control provides a navigational interface	a remote control provides a navigational interface	Same

Item compared	sub category	K213467 EVA NEXUS (Subject Device) (9000.ANTxx/COMyy)	K190875 Predicate device EVA (8000.ANTxx/COMyy)	Equivalence (same / similar / different)
	controller	to the system's GUI, remotely through the IR receiver in the screen	to the system's GUI, remotely through the IR receiver in the screen	
User Interfaces	Digital Overlay	An (optional) Digital Overlay module is available which outputs information from the surgical system for visualization on an external screen. The visualization function may be used to overlay parameters from the surgical system on top of the microscope image for the surgeon or the audience.	Not applicable	Different
Phaco-emulsification				
Phaco-emulsification	Principle of operation	The Phaco Module can be used for Phaco emulsification and fragmentation. The module provides ultrasound power with continuous auto-tuning. The module drives a connected Phaco handpiece. The handpiece contains piezo-electric elements which transforms the electrical drive energy into an ultrasonic output at the distal end of the handpiece needle.	The Phaco Module can be used for Phaco emulsification and fragmentation. The module provides ultrasound power with continuous auto-tuning. The module drives a connected Phaco handpiece. The handpiece contains piezo-electric elements which transforms the electrical drive energy into an ultrasonic output at the distal end of the handpiece needle.	Same
Phaco Module	Design	digitally controlled driver board to drive Ultrasound power Phaco handpiece, for emulsification or fragmentation of lens	driver board to drive Ultrasound power Phaco handpiece, for emulsification or fragmentation of lens	Similar
Power output	Performance requirement	50 ±20% [W]	50 [W]	Same
Phaco frequency	Performance requirement	40kHz Auto-tuning	40kHz Auto-tuning	Same
Phaco stroke length	Performance requirement	80 µm +/-20 µm (for 3002.M handpiece) 100 µm +/-20 µm (for 3002.P handpiece)	80 µm +/-20 µm (for 3002.M handpiece) 100 µm +/-20 µm (for 3002.P handpiece)	Same
Maximum U/S velocity of tip output	Performance requirement	Velocity of tip max. 13.2 m/s (at maximum U/S power, measured in water)	Velocity of tip max. 13.2 m/s (at maximum U/S power, measured in water)	Same
Vitrectomy				
Vitrectomy	Principle of operation	The Vitrectomy module provides pulsed pressurized air to drive a Vitreous cutter (vitrectome) in order to remove some or all of the vitreous humor from the eye to provide better access to the retina for a variety of surgical repairs.	The vitrectomy module provides pulsed pressurized air to drive a Vitreous cutter (vitrectome) in order to remove some or all of the vitreous humor from the eye to provide better access to the retina for a variety of surgical repairs.	Same
Vitrectomy	Design	Driver for pneumatically operated vitreous cutters	Driver for pneumatically operated vitreous cutters	Same
Vitrectomy pulse rate	Performance requirement	single and 20-10000 ppm; tolerance +/- 20% Single cut function	single and 20-8000 ppm; tolerance +/- 20% Single cut function	Similar

Item compared	sub category	K213467 EVA NEXUS (Subject Device) (9000.ANTxx/COMyy)	K190875 Predicate device EVA (8000.ANTxx/COMyy)	Equivalence (same / similar / different)
Vitrectomy cutting rate	Performance requirement	up to 10000 cpm for standard vitrectomes up to 20000 cpm for dual cut vitrectomes	up to 8000 cpm for standard vitrectomes up to 16000 cpm for dual cut vitrectomes	Similar
Diathermy				
Diathermy	Principle of operation	The Diathermy Module provides coagulation for anterior and posterior eye-segment surgery	The Diathermy Module provides coagulation for anterior and posterior eye-segment surgery	Same
Diathermy	Design	digitally controlled driver board to provide energy generated by high frequency currents through a diathermy handpiece to the tissue	driver board to provide energy generated by high frequency currents through a diathermy handpiece to the tissue	Similar
Diathermy Type	Performance requirement	Bipolar Coagulation	Bipolar Coagulation	Same
Diathermy Shape of HF-voltage	Performance requirement	Un-modulated sinusoidal voltage	Un-modulated square voltage	Different
Diathermy frequency	Performance requirement	1 MHz (±10%)	1 MHz (±10%)	Same
Diathermy max. output power	Performance requirement	10 W ±20% (at 100 Ohm)	10 W ±10% (at 150 Ohm)	Similar
Diathermy Voltage (peak-peak)	Performance requirement	180Vp -p max.	200 Vp -p max.	Similar
Fluidics Module	-	-	-	-
Fluidics Module	Principle of operation	To maintain anterior/posterior chamber stability, the pump keeps the pressure of the fluidics in the tubing system to the physician set value, or alternatively keeps the inflow and outflow of the fluidics to the physician set flow value.	To maintain anterior/posterior chamber stability, the pump keeps the pressure of the fluidics in the tubing system to the physician set value, or alternatively keeps the inflow and outflow of the fluidics to the physician set flow value.	Same
Irrigation (infusion)	Principle of operation	Pressurized infusion by a plunger pump. Pressure control by squeezing the membranes of a to the pump connected cartridge.	Pressurized infusion by means of an height controlled Infusion Pole (gravity) or by means of an Air pressurized Infusion bottle.	Different
Irrigation (Infusion) modes	Performance requirement	Modes: Fixed/AIC/SMART IOP	Modes: Gravity/AIC/VGPC	Different
Infusion/Irrigation pressure	Performance requirement	0-150 mmHg	0-150 mmHg	Same
Aspiration	Principle of operation	Plunger pump; can operate in flow control or vacuum control by squeezing the membranes of a to the pump connected cartridge. The pumping system can be used in one of two modes: pressure control or flow control.	Plunger pump; can operate in flow control or vacuum control by squeezing the membranes of a to the pump connected cartridge. The pumping system can be used in one of two modes: pressure control or flow control.	Same
Aspiration	Performance requirement	Flow mode or vacuum mode	Flow mode or vacuum mode	Same

Item compared	sub category	K213467 EVA NEXUS (Subject Device) (9000.ANTxx/COMyy)	K190875 Predicate device EVA (8000.ANTxx/COMyy)	Equivalence (same / similar / different)
Aspiration - flow mode	Performance requirement	Flow mode: Nominal flow 0-90 [ml/min] Vacuum limit 0 to -680 [mmHg@sea level]	Flow mode: Nominal flow 0-90 [ml/min] Vacuum limit 0 to -680 [mmHg@sea level]	Same
Aspiration - vacuum mode	Performance requirement	Vacuum mode: Vacuum 0 to -680 [mmHg@sea level} Rise time 300 [ms] (measured step 0 to 650mm Hg @ 0 cc/min)	Vacuum mode: Vacuum 0 to -680 [mmHg@sea level} Rise time 300 [ms] (measured step 0 to 650mm Hg @ 0 cc/min)	Same
Aspiration - Backflush	Performance requirement	Micro Backflush (Reflux): Pressure range 0-50 [mmHg] Time of activation 0-250 [ms]	Micro Backflush (Reflux): Pressure range 0-50 [mmHg] Time of activation 0-250 [ms]	Similar
		Auto Backflush (Reflux): no user selectable parameters	Auto Backflush (Reflux): Pressure range 0 to 50 [mmHg] Time of Activation 0-250 [ms]	
		Manual Backflush (Reflux): Pressure range: see Infusion/Irrigation	Manual Backflush (Reflux): Pressure range: see Infusion/Irrigation	
		Proportional Backflush: Pressure range 0-50 [mmHg]	Not applicable	
Cartridge and Tubing Sets	Design	The cartridge consists of a collection bag to collect aspiration fluids, tubing for irrigation and aspiration and the tubing for the administration set. Fluid circulation is achieved by the interaction of the membrane and the pump pistons.	The cartridge consists of a collection bag to collect aspiration fluids, tubing for irrigation and aspiration and the tubing for the administration set. Fluid circulation is achieved by the interaction of the membrane and the pump pistons.	Same
Endo-Illumination				
Endo-Illumination	Principle of operation	The Endo-illumination module is used to illuminate the interior of the posterior chamber of the eye, a light source is available in the console, controllable in output, which connects to illumination fibers to bring the light into the eye.	The Endo-illumination module is used to illuminate the interior of the posterior chamber of the eye, a light source is available in the console, controllable in output, which connects to illumination fibers to bring the light into the eye.	Same
Illumination light source	Design	LED source, 3 port connections for endoillumination probes	LED source, 3 port connections for endoillumination probes	Same
Illumination output and accuracy	Performance requirement	40 lm +/-20% (with 20ga fiber)	40 lm +/-20% (with 20ga fiber)	Same
Illumination spectrum	Performance requirement	425 to 680 [nm] UV filter (up to 425 nm), IR filter (above 680 nm)	425 to 680 [nm] UV filter (up to 425 nm), IR filter (above 680 nm)	Same
Illumination Numerical aperture	Performance requirement	up to NA = 0.6	up to NA = 0.6	Same
Air Module				
Fluid/Air exchange	Principle of	The Air Module provides pressurized air for fluid-	The Air Module provides pressurized air for fluid-	Same

Item compared	sub category	K213467 EVA NEXUS (Subject Device) (9000.ANTxx/COMyy)	K190875 Predicate device EVA (8000.ANTxx/COMyy)	Equivalence (same / similar / different)
	operation	air exchange. The pressure can be set on the screen.	air exchange. The pressure can be set on the screen.	
Fluid/Air exchange	Design	Air infusion module to provide air through a connected tubing to the eye. The air is delivered to the tubing set through an extended 0.22µm filter.	Air infusion module to provide air through a connected tubing to the eye. The air is delivered to the tubing set through an extended 0.22µm filter.	Same
Fluid/Air exchange pressure range	Performance requirement	0 - 150 mmHg	0 - 150 mmHg	Same
Fluid/Air exchange pressure accuracy	Performance requirement	<3 mmHg	<3 mmHg	Same
Fluid/Air exchange flow rate	Performance requirement	1200 [ml/min]	1200 [ml/min]	Same
VFC Module				
Viscous Fluid Extraction	Principle of operation	VFE (Viscous Fluid Extraction) is used to extract intraocular viscous fluid from the eye into a syringe. It is done with vacuum.	VFE (Viscous Fluid Extraction) is used to extract intraocular viscous fluid from the eye into a syringe. It is done with vacuum.	Same
Viscous Fluid Extraction pressure	Performance requirement	0 to -660 mmHg	0 to -660 mmHg	Same
Viscous Fluid Injection	Principle of operation	VFI (Viscous Fluid Injection) is used to inject viscous fluid from a syringe into the eye. It can be done with pressurizing a pre-filled syringe.	VFI (Viscous Fluid Injection) is used to inject viscous fluid from a syringe into the eye. It can be done with pressurizing a pre-filled syringe.	Same
Viscous Fluid Injection pressure	Performance requirement	0 - 6 bar	0 - 6 bar	Same
Micro Injection	Principle of operation	MI (Micro Injection) is used to inject a small amount of aqueous fluid though a high gauge delivery device into the eye. It is done by pressurizing a pre-filled syringe.	n/a	Different
Micro Injection	Performance requirement	0 - 2 bar	n/a	Different
Laser				
Laser	Principle of operation	The (optional) Laser Module provides a therapeutic eye Laser device indicated for photo coagulation of both anterior and posterior segments of the eye	The (optional) Laser Module provides a therapeutic eye Laser device indicated for photo coagulation of both anterior and posterior segments of the eye	Same
Treatment laser type	Design	Diode pumped frequency doubled Nd:YAG Laser for photogoagulation, wavelength 532nm	Diode pumped frequency doubled Nd:YAG Laser for photogoagulation, wavelength 532nm	Same
Laser Class	Performance requirement	Class IV	Class IV	Same

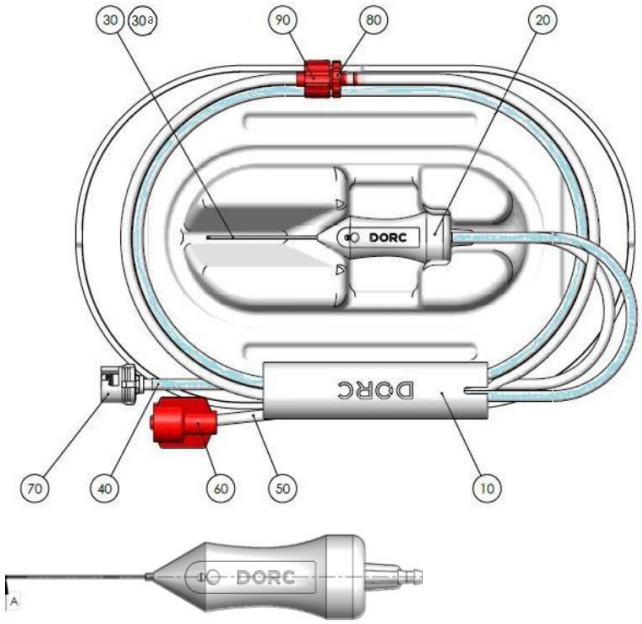
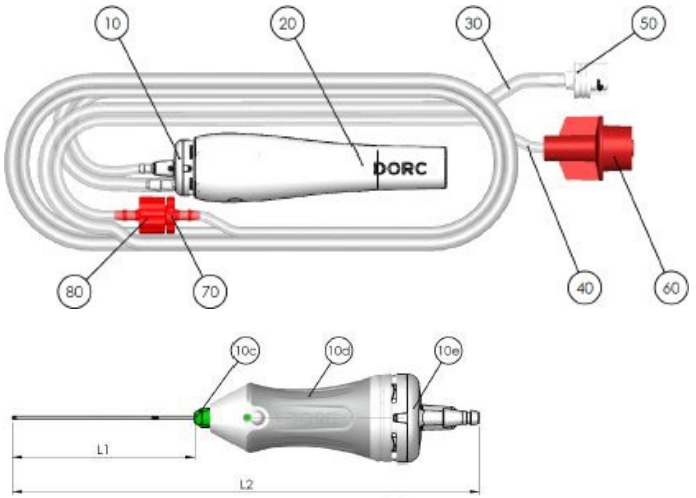
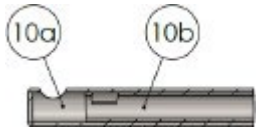
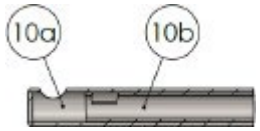
Item compared	sub category	K213467 EVA NEXUS (Subject Device) (9000.ANTxx/COMyy)	K190875 Predicate device EVA (8000.ANTxx/COMyy)	Equivalence (same / similar / different)
Laser Modes	Performance requirement	Single shot, pulsed or continuous mode	Single shot, pulsed or continuous mode	Same
Laser wavelenght	Performance requirement	Green - 532 nm ±5 nm	Green - 532 nm ±5 nm	Same
Laser power	Performance requirement	0.05-1.2 W ±20%	0.05-1.2 W ±20%	Same
Laser pulse duration	Performance requirement	50-5000 ms	50-5000 ms	Same
Laser interpulse time	Performance requirement	50-5000 ms	50-5000 ms	Same
Aiming beam wavelength	Performance requirement	red - 630 - 645 nm	red - 630 - 645 nm	Same
Aiming beam power	Performance requirement	less than 1 mW	less than 1 mW	Same
Other				
Software	Operating system	Windows embedded OS	Windows embedded OS	Same
	Application	EVA NEXUS GUI for parameter setting, interfaces for operator to control different modules, and service purpose.	EVA GUI for parameter setting, interfaces for operator to control different modules, and service purpose.	Similar
Preventive measures and warnings	Device/GUI/IFU	Relevant safety signs and warnings are included on the device, in the EVA NEXUS Graphical user interface and the User Manual	Relevant safety signs and warnings are included on the device, in the EVA Graphical user interface and the User Manual	Similar
Packaging	Console	Plastic dust cover and protective flight case or carton	Plastic dust cover and protective flight case or carton	Similar
	Accessories	Disposable - Primary EO sterilization package and protective box Reusable - Protective packaging	Disposable - Primary EO sterilization package and protective box Reusable - Protective packaging	Same
Labelling	Labels	Labels according to international standards including safety signs for both console and accessories	Labelling according to international standards including safety signs for both console and accessories	Same
	User manual	Full user manual available and delivered with the system	Full user manual available and delivered with the system	Similar

6. Device Description

The EVA NEXUS™ Ophthalmic Surgical System (EVA NEXUS) is a combined anterior and posterior procedure ophthalmic system that is modular in design and is identical in most respects to the recently cleared predicate EVA Ophthalmic Surgical System (K190875). EVA NEXUS (see Figures 1, and 2 for external views) is designed for use in anterior and posterior procedures that require infusion, vitreous cutting, aspiration, illumination, irrigation, lens emulsification and fragmentation, cautery, diathermy as well as photocoagulation.

The vitrectomy probes to be used with the EVA NEXUS™ Ophthalmic Surgical System are identical in function to those cleared with the EVA Ophthalmic Surgical System (K142877). Specifically, for EVA NEXUS a new TDC (Two directional cutter) vitrectome was developed to support the maximum cutting frequency of 10,000 cycles per minute. A comparison between the cleared vitrectome and the vitrectome under evaluation is given in table 1.

Table 1 Comparison of predicate vitrectomy probes and vitrectomy probes under evaluation.

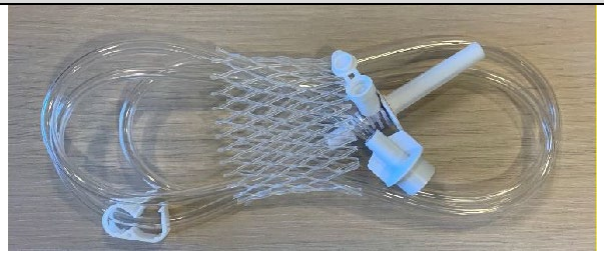
Items	Predicate vitrectomy probe (K142877)		Subject Device	
Device name	Disposable High Speed TDC Cutter		Two Dimensional Cutter	
Model	23G: 8268.VIT23 25G: 8268.VIT25 27G: 8268.VIT27		23G: 9268.VIT23 25G: 9268.VIT25 27G: 9268.VIT27	
Construction				
	 10a – Outer knife 10b – Inner knife	10 – Extension handle 20 – Vitrectome body 30, 30a – Outer & inner knives 40 – Pressure tubing 50 – Aspiration tubing 60, 70, 80, 90 – Connectors	 10a – Outer knife 10b – Inner knife	10 – Vitrectome 10c – Hub (colour indicates gauge size) 10d – Body, 10e - Cap 20 – Extension handle 30 – Pressure tubing 40 – Aspiration tubing 50, 60, 70, 80, connectors
Packaging	Supportive packaging: tray, tape Sterile packaging: peel pouch		Supportive packaging: elastic tubular net & extension handle	

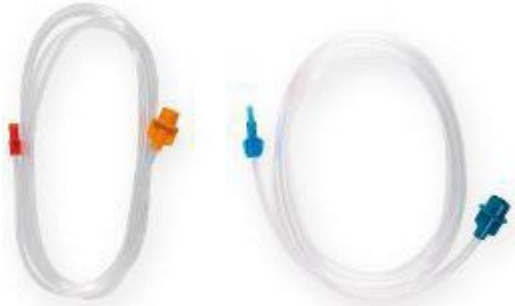
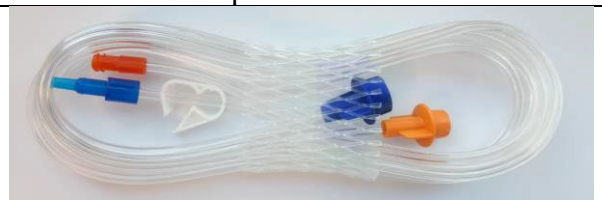
Items	Predicate vitrectomy probe (K142877)	Subject Device
	Outer packaging: carton box	Sterile packaging: peel pouch Outer packaging: carton box
Basic principles (operation principles/ mechanism)	To remove vitreous from the posterior chamber of the eye via a cutting and aspiration function; Cutting action is performed via forward motion and backward motion of the inner knife via pneumatic pressure from surgical system and a spring.	To remove vitreous from the posterior chamber of the eye via a cutting and aspiration function; Cutting action is performed via forward motion and backward motion of the inner knife via pneumatic pressure from surgical system and a spring.
Structural composition	The device consists of following main components: body with pneumatic pressure chamber and spring, inner & outer knife, tubing with connectors for pneumatic air from surgical system and aspiration of eye fluids to the cartridge of the surgical system and an extension handle. This product does not contain electrical connection or electrical components and the product is disposable.	The device consists of following main components: body with pneumatic pressure chamber and spring, inner & outer knife, tubing with connectors for pneumatic air from surgical system and aspiration of eye fluids to the cartridge of the surgical system and an extension handle. This product does not contain electrical connection or electrical components and the product is disposable.
Materials	Body, extension handle: PC; Knives: AISI 304, phynox; Tubing: PVC Connectors: Nylon and PVC	Body, hub, cap, extension handle: PC; Knives: AISI 304, phynox; Tubing: PVC Connectors: Nylon and PVC
Performance	Compatibility with surgical system: EVA and EVA NEXUS, when taking into account the maximum driving frequency.	Compatibility with surgical system: EVA NEXUS
	Driving frequency: 20-8000 CPM, ±20%	Driving frequency: 20-10,000 CPM, ±20%
	8268.VIT23	9268.VIT23
	Shaft diameter: 23G / 0.64 mm	Shaft diameter: 23G / 0.64 mm
	Shaft length: 33.0 mm	Shaft length (L1 in drawing above): 33.0 mm
	8268.VIT25	9268.VIT25
	Shaft diameter: 25G / 0.53 mm	Shaft diameter: 25G / 0.53 mm
	Shaft length: 28.5 mm	Shaft length: 27 mm
	8268.VIT27	9268.VIT27
	Shaft diameter: 0.43 mm	Shaft diameter: 0.43 mm
	Shaft length: 8268.VIT27: 28.5 mm	Shaft length: 8268.VIT27: 27 mm

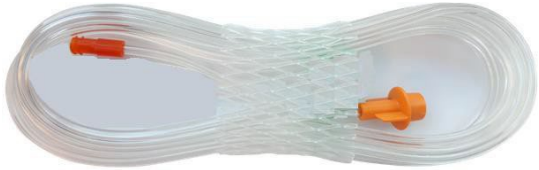
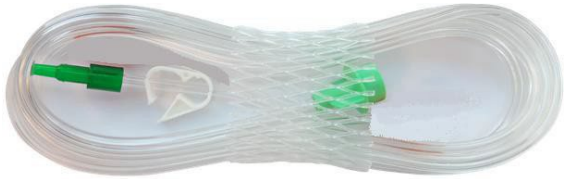
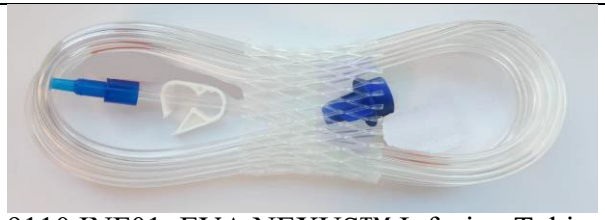
Items	Predicate vitrectomy probe (K142877)	Subject Device
Sterilization method	EO	EO
Indication	It is used for ophthalmic vitrectomy and is used together with an ophthalmic surgical system.	It is used for ophthalmic vitrectomy and is used together with an ophthalmic surgical system.
method of application	Handled by scrub nurse, circulating nurse, used by eye surgeon; 1) connected to surgical system via pilot tube and aspiration tube 2) cutting frequency and aspiration level set via GUI on surgical machine 3) control of cutting speed and aspiration level by surgeon via footswitch	Handled by scrub nurse, circulating nurse, used by eye surgeon; 1) connected to surgical system via pilot tube and aspiration tube 2) cutting frequency and aspiration level set via GUI on surgical machine 3) control of cutting speed and aspiration level by surgeon via footswitch

The tubing sets and luer connectors utilized for the EVA NEXUS are similar to those cleared with the EVA Ophthalmic Surgical System (K142877). However, since EVA NEXUS no longer has a height adjustable infusion pole and it now includes an additional infusion / irrigation port, tubing adjusted to that has been developed. The additional tubing has the same material as the existing tubing and same connector types, however the connector has a different colour in order to clearly distinguish it and make it unique for connection. The infusion line was changed by removing the dripchamber. Table 2 below shows a comparison between previously cleared (right) and new (left) tubing. In the figure, the following connectors are present: White for infusion giving, from BSS container to cartridge. Blue for infusion of BSS from cartridge to the eye. Green for irrigation e.g. to a phaco handpiece. Red for aspiration from vitrectomy cutter to the cartridge collection bag. Orange for auxilliary aspiration e.g. from a phaco handpiece to the cartridge collection bag. Air tubing is used in certain surgical procedures to transport air to the surgical site, commonly done through separate tubing. In these cases the BSS is replaced by air from the surgical system, and the intraocular pressure will be controlled by the air pressure. All tubing is sterilized by means of ethylene oxide.

Table 2 Comparison of predicate tubing and tubing under evaluation.

Items	**EVA NEXUS tubing (new)**	**EVA tubing (K142877)**
Picture Product code Product name	 9110.INP01: EVA NEXUS™ Infusion Giving set	 8110.INP01: Disposable EVA Gravity Input set
Sterile packaging	Peel pouch	Peel pouch
Operating principle	The Infusion Giving set is connected between the container with BSS and the cartridge to provide BSS to the surgical system	The gravity input set is connected between the container with BSS and the cartridge to provide BSS to the surgical system
Materials	Connector and tubing: PVC	Connector and tubing: PVC

	Spike, cap, filter: ABS, PE, ACP, PP Clamp: PP	Dripchamber incl. Spike, cap, filter: PVC, ABS, PE, ACP, PP, Versapor Clamp: PP
Size	Length: 1200 mm Inner Diameter: 4 mm	Length: 1900 mm Inner Diameter: 4 mm
Picture Product code Product name	 9110.IAD01: EVA NEXUS™ Irrigation and Aux. Aspiration Tubing	 8110.IAD01: Disposable EVA Irrigation and Aspiration Tubing
Sterile packaging	Peel pouch	Peel pouch
Operating principle	The irrigation tubing is used to provide BSS to the surgical site. The auxiliary aspiration tubing is used to transport fluids from the surgical site to the surgical system.	The irrigation tubing is used to provide BSS to the surgical site and the aspiration tubing is used to remove fluids from the surgical site.
Materials	Connector and tubing: PVC Clamp: PP	Connector and tubing: PVC
Size	Length: 1900 mm Inner Diameter irrigation: 4 mm Inner diameter aspiration: 1.5 mm	Length: 1900 mm Inner Diameter irrigation: 4 mm Inner diameter aspiration: 1.5 mm
Picture Product code Product name	 9110.IAD02: EVA NEXUS™ Infusion and Aux. Aspiration Tubing	See 8110.IAD01
Sterile packaging	Peel pouch	Peel pouch
Operating	The infusion tubing is used to transport BSS from the	The irrigation tubing is used to provide BSS to the

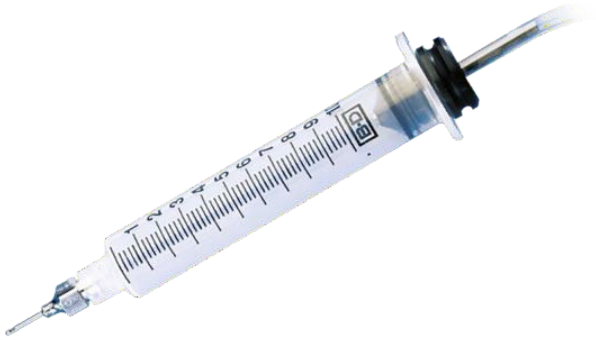
principle	surgical system to the surgical site. The auxiliary aspiration tubing is used to transport fluids from the surgical site to the surgical system.	surgical site and the aspiration tubing is used to remove fluids from the surgical site.
Materials	Connector and tubing: PVC Clamp: PP	Connector and tubing: PVC
Size	Length: 1900 mm Inner Diameter infusion: 4 mm Inner diameter aspiration: 1.5 mm	Length: 1900 mm Inner Diameter irrigation: 4 mm Inner diameter aspiration: 1.5 mm
Picture Product code Product name	 9110.AAS01: EVA NEXUS™ Aux. Aspiration Tubing	This is the same tubing as the Auxilliary aspiration tubing in 9110.IAD01 and 9110.IAD02
Picture Product code Product name	 9110.IRR01: EVA NEXUS™ Irrigation Tubing	This is the same tubing as the irrigation tubing in 9110.IAD01
Picture Product code Product name	 9110.INF01: EVA NEXUS™ Infusion Tubing	This is the same tubing as the infusion tubing in 9110.IAD02

In order to use a surgical system to aid with the injection and/or extraction an adaptor kit to the surgical system should be used.

When the surgeon has to inject fluids into the eye the volume of the injected fluid could vary. Therefore, the surgeon requires a system to inject fluid with a 1 cc syringe.

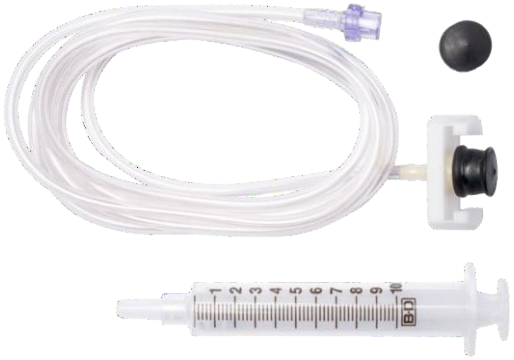
Pictures of the injection and extraction kits can be found below. A comparison between 1364.DD (to be used with the Micro Injection capability) and the equivalent 1363.DD which was cleared in K142877 is shown in table 3.

1362.D



1362.VFE2

1363.DD



1362.VFE

1279.VFI

1364.DD (changed)

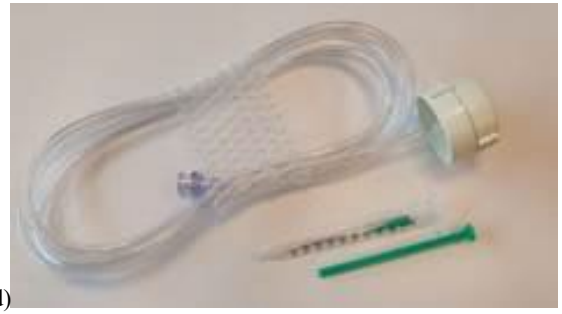


Table 3 Comparison of predicates and proposed device 1364.DD

Feature	**Device under evaluation 1364.DD - 1 cc syringe holder for micro injection**	**MicroDose™ Injector (MedOne)**	**Orbit Subretinal Delivery System (Orbit SDS)**
K#	K213467	K203264	K200325
Device classification / Code	Class II FMF, Syringe, Piston 21 CFR 880.5860	Class II FMF, Syringe, Piston 21 CFR 880.5860	Class II FMF, Syringe, Piston 21 CFR 880.5860
Secondary product classification / code	N/A	N/A	Class I HMX, Ophthalmic Cannula 21 CFR 886.4350
Indication for Use	The 1364.DD is indicated for micro-injection into the subretinal space.	The MicroDose is indicated for low volume ophthalmic injection into the subretinal space.	The Orbit Subretinal Delivery System is indicated for micro injection into the subretinal space.
How Supplied	Sterile, single use only	Sterile, single use only	Sterile, single use only
Configuration	1 mL syringe (syringe barrel and piston, plunger separated from barrel), Tubing with snap collars on syringe end and connector on surgical system end	1 mL Syringe (syringe barrel and piston – plunger removed) and Connector	1 mL Syringe (syringe barrel, plunger and piston), Cannula, Tubing set, connector for surgical system, Magnetic pad, Ophthalmic marker
Mode of Operation	Pneumatic	Pneumatic	Pneumatic or Manual
Volume	1 mL	1 mL	1 mL
Fluid delivery	Cannula sold separately	Cannula sold separately	Cannula supplied with the device
Biocompatibility	Meets ISO 10993-1	Meets ISO 10993-1	Meets ISO 10993-1

The laser probes to be used with EVA NEXUS will be available with various tip shapes. The laser probes are the same as used for the predicate EVA Ophthalmic Surgical System (K190875), are purchased from Peregrine and were cleared in K024061, K031023, and

K132614. In addition, DORC wishes to include directional laser probes; examples are shown below (7225.DORC). These laser probes are similar in materials to the cleared laserprobes, but have a sliding mechanism, which allows the surgeon to retract the laser fiber when inserting it through a trocar cannula and extending it inside the eye, allowing it to reach the peripheral area of the retina.

7525.DORC

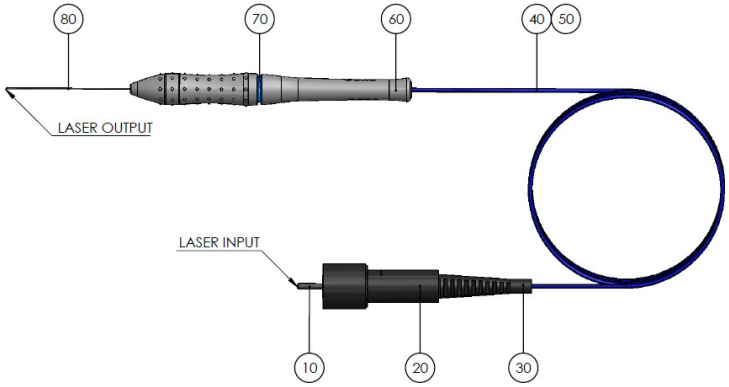
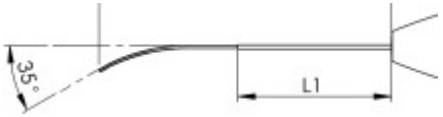
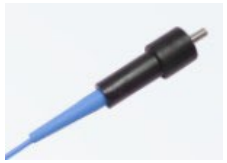
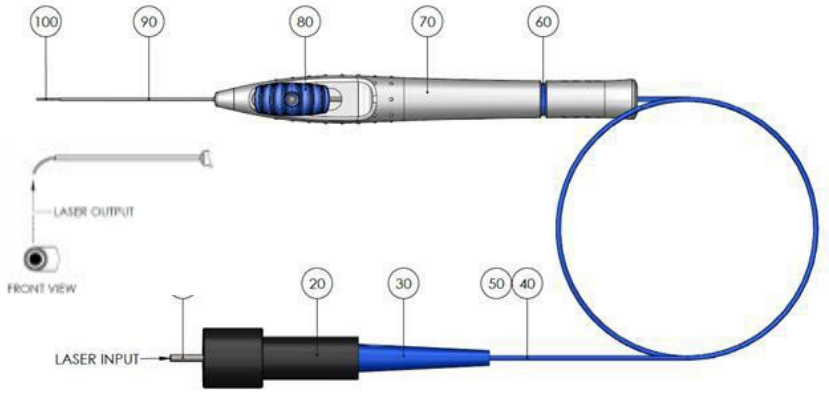
Stepped laser probe 25 gauge / 0.5 mm

7225.DORC

Directional laser probe (25 gauge / 0.5 mm)

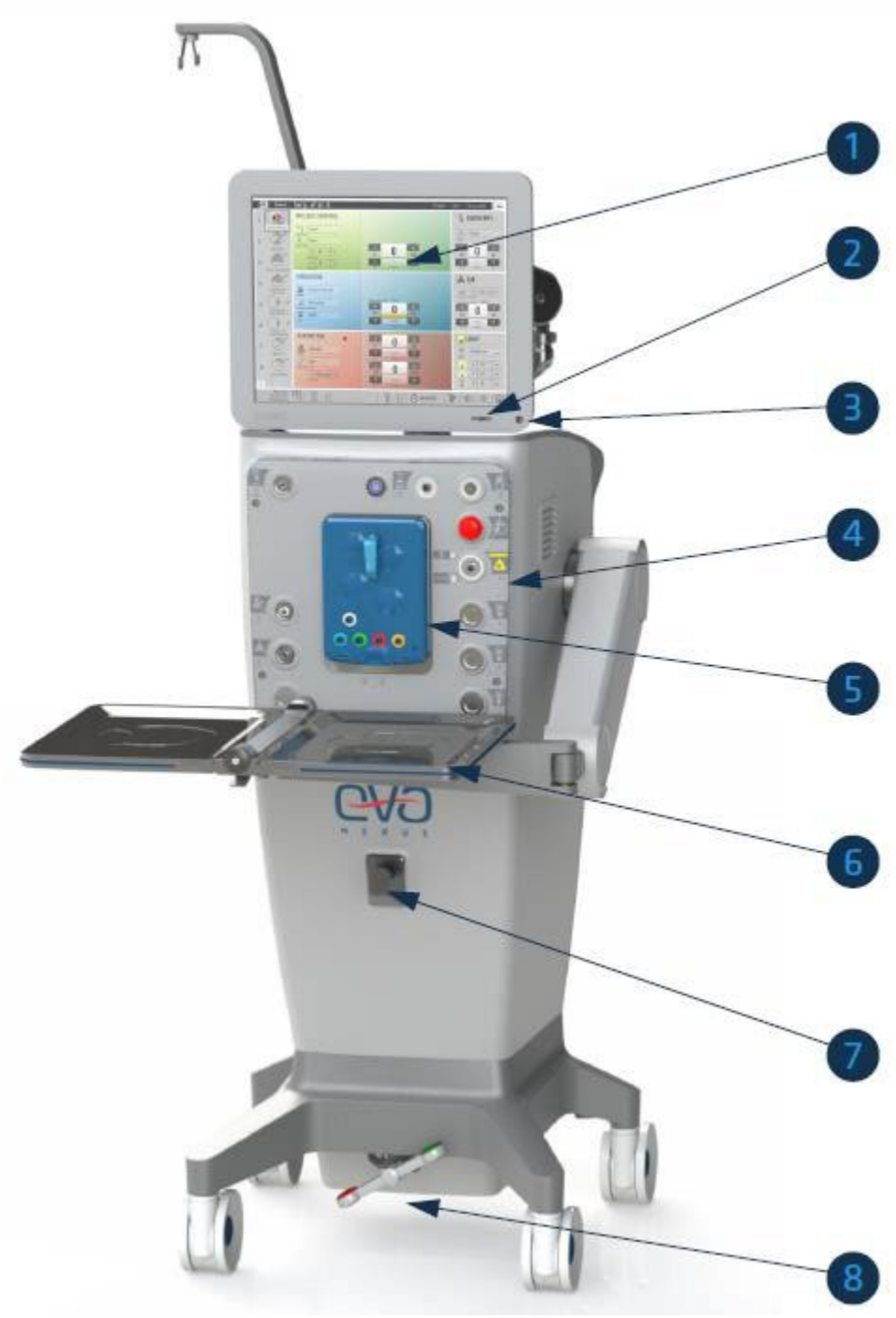
Table 4 gives a comparison between the cleared laserprobe and the directional laser probe under evaluation.

Table 4 Comparison of predicate laser probes and laser probes under evaluation.

Items	Predicate laser probe (K024061)	Device under evaluation
Device name	Stepped laser probe 25 gauge / 0.5 mm	Directional laser probe (25 gauge / 0.5 mm)
Model	7525.ALC and 7525.DORC	7225.ALC and 7225.DORC
Construction	 7525.ALC   Connector of 7525.DORC	 7225.DORC    Connector of 7225.ALC
	10 – SMA Connector 20 – Connector bushing 30 – Strain relief boot 40 – Jacket 50 – Optical fiber 60 – Handpiece 70 – O-ring 80 - Needle	10 – SMA Connector 20 – Connector bushing 30 – Strain relief boot 40 – Jacket 50 – Optical fiber 60 – O-ring 70 – Handpiece 80 – Slide knob 90 – Needle 100 – Tip 110 - Cap
Packaging	Peel pouch	Peel pouch
Basic principles (operation principles/ mechanism)	A laser probe that transfers laser light (energy) from laser energy source in surgical system via the tip of the device to the retina to locally reattach retinal detachments. The shaft can be straight, curved or directional to facilitate easy access to all locations on the retina (including the periphery).	A laser probe that transfers laser light (energy) from laser energy source in surgical system via the tip of the device to the retina to locally reattach retinal detachments. The shaft can be straight, curved or directional to facilitate easy access to all locations on the retina (including the periphery).
Structural composition	The product is composed of laser connector, handpiece and probe protector.	The product is composed of laser connector, handpiece with sliding mechanism and probe protector.

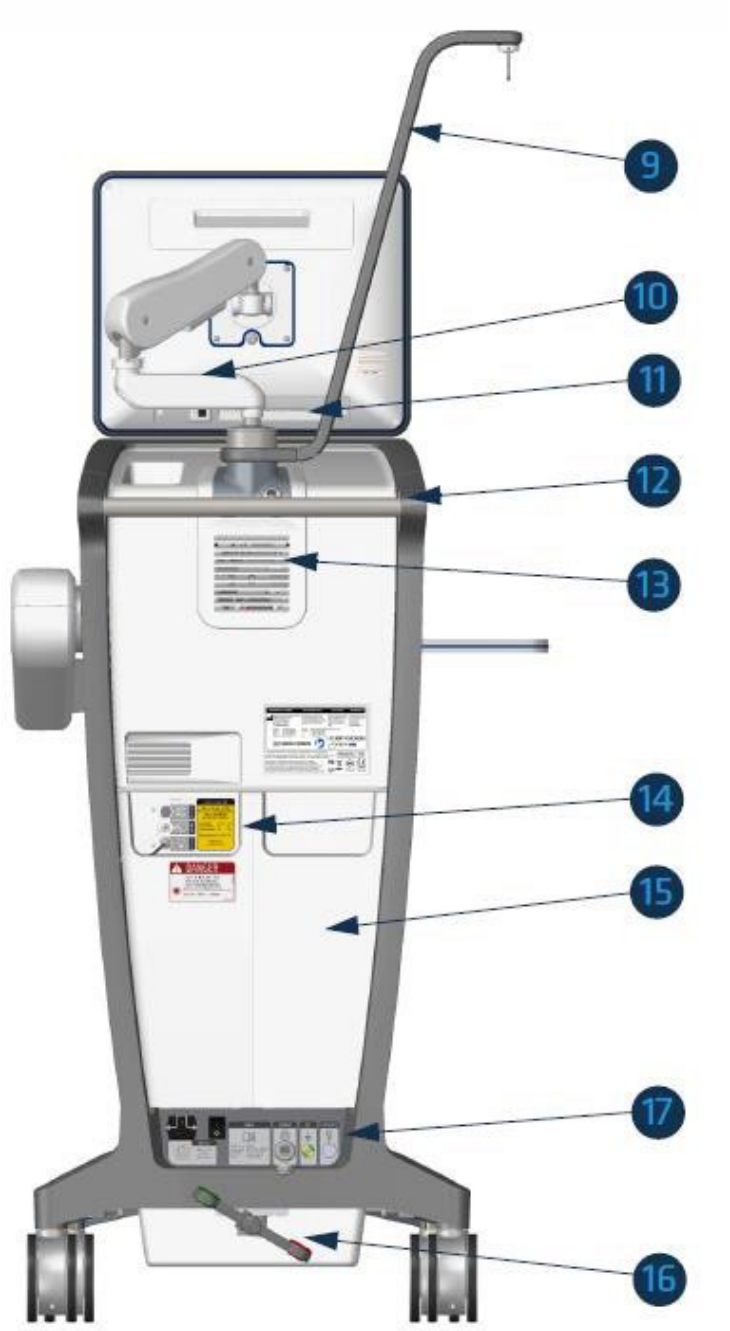
Items	Predicate laser probe (K024061)	Device under evaluation
Materials	Nickel plated Brass / CuNiZn, Neoprene, Acrylated Olefin, Glass, Hard Clad Silica, ETFE, POM, Silicone, Stainless Steel, Nitinol, PMMA	Nickel plated Brass / CuNiZn, Neoprene, Acrylated Olefin, Glass, Hard Clad Silica, ETFE, POM, Silicone, Stainless Steel, Nitinol, PMMA, PC, PP
Performance and mechanical properties	Compatibility with surgical system: EVA and EVA NEXUS	Compatibility with surgical system: EVA and EVA NEXUS
	.ALC is meant for use on machines with SMA connector .DORC is meant for use on machines with a DORC connector	.ALC is meant for use on machines with SMA connector .DORC is meant for use on machines with a DORC connector
	7025.ALC and 7025.DORC	7225.ALC and 7225.DORC
	Total length: 256 cm ± 10 cm	Total length: 256 cm ± 10 cm
	Core diameter: 200 µm	Core diameter: 200 µm
	Beam divergence angle: 210 mrad	Beam divergence angle: 210 mrad
	Fiber tensile strength: at least 5N	Fiber tensile strength: at least 5N
Sterilization method	EO	EO
Indication	The product is used in conjunction with 532nm laser for laser light transmission	The product is used in conjunction with 532nm laser for laser light transmission
method of application	Handled by scrub nurse, circulating nurse, used by eye surgeon; 1) connected to surgical system via connector 2) laser power output set via GUI on surgical machine 3) activation of laser function by surgeon via footswitch	Handled by scrub nurse, circulating nurse, used by eye surgeon; 1) connected to surgical system via connector 2) laser power output set via GUI on surgical machine 3) activation of laser function by surgeon via footswitch

Figure 1: EVA NEXUS™ (Front)



- Display with touch screen
- Infrared receiver (remote control)
- Holder for touch screen pen
- Instrument connections and buttons
- Cartridge (Irrigation/Infusion/Aspiration)
- Mayo arm and tray
- Footswitch holder
- Brake lever

Figure 2: EVA NEXUS™ (Back)



- Bottle holder
- Monitor arm
- USB port [a]
- Push bar
- Cooling outlet
- Laser connections
- Storage Compartment (documentation, hoses, tubes and power cord)
- Brake lever
- Supply connections, Fuse, Mains switch, Ethernet port and Footswitch.

a.Note: The USB port is restricted to use of an USB storage device only.

7. Comparison of Technological Characteristics with the Predicate Devices

There are no indications for use, features or technological of the EVA NEXUS™ Ophthalmic Surgical System that have not been previously cleared in the predicate devices.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

BIOCOMPATIBILITY TESTING

The biocompatibility evaluation of the EVA NEXUS™ Ophthalmic Surgical System was conducted in accordance with FDA Guidance "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process", issued on September 4, 2020.

The EVA NEXUS ™ Ophthalmic Surgical System is not intended to come into contact with the patient.

Surgical System that potentially come into contact with the patient or patient fluid path have been previously cleared. Since new vitrectomes, tubing, phaco needles and sleeves and directional laser probes are introduced in this 510(k), the most recent biocompatibility testing is provided in Annex 4.

Biocompatibility testing of accessories has been conducted and confirmed acceptable by cytotoxicity, Kligman maximization and intracutaneous irritation testing, in compliance with ISO 10993-1, 10993-5, 10993-10 and 10993-12.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)

Electrical safety and EMC testing were conducted on the EVA NEXUS™ Ophthalmic Surgical System. The system complies with the IEC 60601-1, IEC 60601-2-2 and IEC 80601-2-58 standards for safety and EN 60601-1-2 and 47 CFR Part 15 Subpart B for EMC.

SOFTWARE VERIFICATION AND VALIDATION TESTING

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket

Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

PERFORMANCE (BENCH) TESTING

Although animal and clinical performance testing were not required for the EVA NEXUS to demonstrate efficacy, safety and substantial equivalence to predicate devices, a variety of laboratory (bench) performance tests have been conducted including:

- Testing to ensure compliance to ISO 15004-2: 2007 "Illuminator Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection"
- Testing to ensure compliance to IEC 60601-2-22:2007, A1:2012, Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment is reported in 2230157.50D.
- EVA pneumatic compatibility test which concludes that no changes that might impact Nitrogen-compatibility are introduced in EVA NEXUS when compared to the predicate EVA. Therefore EVA NEXUS is compatible with compressed nitrogen (N_2) and is in that sense substantially equivalent to the predicate EVA.
- EVA pneumatic compatibility test: RPRT 30554100 which concludes that no changes that might impact Nitrogen-compatibility are introduced in EVA NEXUS when compared to the predicate EVA. Therefore EVA NEXUS is compatible with compressed nitrogen (N_2) and is in that sense substantially equivalent to the predicate EVA.
- EVA / EVA NEXUS Performance comparison test report: RPRT 30609300. This report includes a comparison between EVA NEXUS and the predicate EVA, regarding the functions: irrigation, aspiration, and micro injection in relation to IEC 80601-2-58:2016. The report concludes that the functions are very similar, substantiating the substantial equivalence between EVA NEXUS and the predicate EVA.
- RPRT 30572000 EVA Reliability Prediction report gives a prediction on the system and subsystem failure rate using the Telcordia Issue 3 model.
- Disposable Pneumatic Vitrectomes Product Verification Report: RPRT 30612000 shows that the vitrectomes can withstand an overpressure of 4.5 bar (65psi). The same report is used to show that the vitretomes function as intended throughout the life time of the device, by means of

lifetime (5 minutes at 5000 CPM and 5 minutes at maximum cut rate) and durability tests (≥ 150,000 cutting cycles).

- EVA NEXUS Cartridge Verification Report: RPRT 30518300 shows that the cartridge designed for EVA NEXUS is substantially equivalent to the EVA cartridge.
- Testing to ensure compliance to IEC 80601-2-58 " Medical electrical equipment, Part 2: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery"
- Testing to ensure compliance to IEC 60601-2-2 " Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories"

Performance data:

The following tests were successfully performed with DORCs 1364.DD to establish substantial equivalence to the predicate devices:

- Biocompatibility testing in accordance with ISO 10993-1 including cytotoxicity (ISO 10993-5) as reported in RPRT 30527100 which was included in VOL024 of the original submission of K213467. Since the syringe used in the 1364.DD has a 510(k) (K063280) additional biocompatibility testing is deemed not required.
- Sterilization validation in accordance with ISO 11135 as reported in chapter 14.1.3 of the original submission of K213467. An adoption (see 2020031_STER) is prepared to record the rationale for adopting the validation criteria and validation test results, which concluded that the product is less worst case as defined in the current validated sterilization process and therefore the mentioned product is adopted.
- Shelf life testing was conducted as reported in chapter 14 of the original submission of K213467. An adoption (see attached 2015052_SLAD) was prepared to provide a rationale to demonstrate that the selected packaging system is considered adequate in protecting the device during storage throughout the specified shelf life. The adoption concluded that the 1364.DD is less worst case than the products included in the shelf life study as referred to in Chapter 14 of the original submission. Therefore revalidation is considered not necessary and the conclusion from the reports is adopted for the 1364.DD.
- Performance tests on sterilized products are performed as reported in RPRT 30492800, section 7.14 (see attached). The tests were all performed successfully.
- Package and performance testing was performed post shipping to ensure package integrity and functionality of the device as reported in chapter 14 of the original submission of K213467. An adoption (see attached 2015052_PIAD) was prepared to demonstrate that the selected packaging system is considered adequate in protecting the device during transport and distribution of shipping units. The adoption concludes that the 1364.DD is not worst case when compared to the products included in earlier packaging studies. Therefore the studies are deemed to be applicable for 1364.DD.

9. Conclusion

As described in this 510(k) Summary, all testing deemed necessary was conducted on the EVA NEXUS™ Ophthalmic Surgical System to ensure that the device is substantially equivalent to the predicate device for its intended use when used in accordance with its Instructions for Use.

The 1364.DD "1 cc syringe holder for micro injection" shares the same intended use, the same or similar device operation, and overall technical and functional capabilities to the predicate devices and meets applicable standards. Any difference between the 1364.DD and the predicate devices has no significant influence on safety or effectiveness of the 1364.DD. Therefore the 1364.DD "1 cc syringe holder for micro injection" is substantially equivalent to the predicate devices.