April 14, 2023

Johnson & Johnson Surgical Vision, Inc.
Amanda Houston
Senior Regulatory Affairs Project Lead
31 Technology Drive
Irvine, CA 92618

Re: K223566
Trade/Device Name: ELITA™ Femtosecond Laser System, ELITA™ Patient Interface
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: March 14, 2023
Received: March 15, 2023

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,

J Angelo Green -S

*for* Tieuvi Nguyen, Ph.D.,
Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223566

Device Name
ELITA™ Femtosecond Laser System, ELITA™ Patient Interface

Indications for Use *(Describe)*
The ELITA™ Femtosecond Laser System is an ophthalmic femtosecond laser indicated in the creation of corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea.

The ELITA™ Femtosecond Laser System is used in conjunction with a sterile disposable Patient Interface, consisting of a pre-sterilized suction ring assembly and pre-sterilized applanation cone, intended for single-use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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

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# 510(k) SUMMARY

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

**510(k) Summary:** K223566

## [807.92(a)(1)] Submitter Information

**Sponsor/Submitter:** AMO Manufacturing USA, LLC
510 Cottonwood Drive
Milpitas, CA 95035 USA
Phone 408-273-5166
Fax:408 273-5966

**Contact Person:** Amanda Houston
Senior RA Program Lead
Email: ahousto1@its.jnj.com
Phone: 562-774-8122

**Date Summary Prepared:** April 6, 2023

## [807.92(a)(2)] Name of Device

**Device Trade Name:** **ELITA™** Femtosecond Laser System, **ELITA™** Patient Interface

**Common Name:** Ophthalmic laser

**Device Classification:** Class II

**Regulation Number:** 21 CFR 886.4390

**Classification Name:** Ophthalmic Laser

**Product Code:** OOE

## [807.92(a)(3)] Legally Marketed Devices

**Primary Predicate:** Femto LDV Z8 Femtosecond Surgical Laser - K213559, Cleared April 21, 2022 (specific to Regulation # 886.4390)

**Secondary Predicate:** iFS Advanced Femtosecond Laser System - K141852; cleared January 16, 2015 (specific to intended use and technology)

| [807.92(a)(4)] Device Description | |
|---|---|
| **Device Description:** | The **ELITA™** Femtosecond Laser System is an ophthalmic laser for corneal surgical operation. The system accurately cuts corneal tissue through a high pulse repetition rate and ultra-fast scanner to place pulses tightly next to each other, generating a continuous cutting surface. The system is controlled by the graphical user interface and software real-time controls. The optical delivery system determines a 3-dimensional position in the cornea at which the laser focuses. When the laser is emitted, the energy delivered is sufficient to photo-disrupt a small volume of tissue. The process of cutting involves repetitively setting a focus point and translating the laser cutting line generated by the resonant scanner.<br><br>The **ELITA™** Femtosecond Laser System is a CDRH Class IV laser per 21 CFR 1040.10 and 1040.11 due to intentional laser exposure of the eye. |
| **[807.92(a)(5)] Intended Use** | |
| **Indications for Use:** | The **ELITA™** Femtosecond Laser System is an ophthalmic femtosecond laser indicated in the creation of corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea.<br><br>The **ELITA™** Femtosecond Laser System is used in conjunction with a sterile disposable **ELITA™** Patient Interface, consisting of a pre-sterilized suction ring assembly and pre-sterilized applanation cone, intended for single-use. |
| **Difference in Indications from Predicate Device** | The **ELITA™** Femtosecond Laser System maintains a similar, more concise Indications for Use statement as that of the FEMTO LDV™ and iFS Systems. This reduction does not impact the intended use, and the main indication (corneal lamellar resection and flap creation) remains the same. There are no new indications/intended use introduced with the **ELITA™** Femtosecond Laser System and **ELITA™** Patient Interface. Therefore, the Indications for Use for these devices are substantially equivalent. |
| **[807.92(a)(6)] Technical Characteristics** | |
| **Technological Characteristics:** | The **ELITA™** Femtosecond Laser System and **ELITA™** Patient Interface (PI) share the same design principle and mode of operation with the predicate devices, in that these systems |

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| | deliver femtosecond pulses through a computer-controlled delivery system to produce a pattern of photo-disruption to create cuts or separation of corneal tissue, resulting in the same functionality (flap creation for LASIK surgery or other surgeries requiring lamellar resection). The **ELITA™** PI characteristics are the same as the iFS PI in that the means of patient contact to the system is created via affixing a suction ring to the scleral surface of the eye prior to use, applanating the eye via vacuum, to couple the beam output to the cornea and provide a fixed reference plane for precision scanning. |

**[807.92(b)(1)] Determination of Substantial Equivalence**

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| **Non-Clinical Performance Data:** | The **ELITA™** Femtosecond Laser System and **ELITA™** Patient Interface successfully completed bench testing, Electromagnetic Compatibility (EMC) testing, and software and design verification and validation testing, which demonstrates the system's ability to meet all intended design specifications.<br><br>Bench testing of the iFS predicate device is directly applicable to the subject device as there are no significant changes to the subject device. Features introduced with the subject device have minor technological differences and do not adversely affect the safety and effectiveness of the device. Additional tests are performed to verify these features function as intended and meet applicable design requirements.<br><br>Bench testing, when coupled with software verification and validation testing presented for the subject device, provides reasonable assurance that the system remains safe and effective for its intended use and furthermore, that it is substantially equivalent to the iFS predicate device.<br><br>Clinical Data was deemed not necessary for the **ELITA™** Femtosecond Laser System and **ELITA™** Patient Interface. The performance data demonstrated that the device performs as intended. |
| **Clinical Performance Data:** | The subject device does not include any changes to the indications for use or intended use of the primary or secondary predicate devices. It does not introduce any new harms or unacceptable risks, and therefore does not require clinical testing to assess safety and performance or to demonstrate equivalence. |

**Table 1** below provides a comparison of the predicate and subject devices and demonstrates substantial equivalence to the predicate devices for its indications for use, intended use, technological characteristics, and new features.

**Table 1: Substantial Equivalence Table**

| Attribute | Subject Device | Primary Predicate | Secondary Predicate |
|---|---|---|---|
| 510(k) Number | K223566 | K213559 | K141852 |
| Trade/ Device Name | **ELITA™** Femtosecond Laser System | FEMTO LDV™ Z8 Femtosecond Surgical Laser Device | iFS Advanced Femtosecond Laser System |
| Manufacturer | AMO Manufacturing USA, LLC | SIE AG, Surgical Instrument Engineering | AMO Manufacturing USA, LLC |
| Regulation Number | 886.4390 | Same | 878.4810 |
| Regulation Name | Ophthalmic Laser | Same | General & Plastic Surgery |
| Regulatory Class | Class II | Class II | Same |
| Product Code | OOE | Same | GEX, HNO |
| Technological Characteristics | Femtosecond pulsed laser | Same | Same |
| Operating Principle | Cutting/resection of the corneal tissue within controlled parameters through the use of femtosecond laser pulses which are delivered through an applanation device that fixates the eye under a vacuum | Same | Same |
| Resection Method | Resection created by laser micro-photo-disruption | Same | Same |
| Indications for Use | The ELITA™ Femtosecond Laser System is an ophthalmic femtosecond laser indicated in the creation of corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial | The FEMTO LDV™ Z8 Femtosecond Surgical Laser is an ophthalmic surgical laser intended for use in the creation of corneal incisions indicated for use in patients undergoing LASIK surgery, tunnel creation for implantation of rings, pocket creation for implantation of | • In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea<br>• In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments |

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| | lamellar resection of the cornea. | corneal implants, lamellar keratoplasty, penetrating keratoplasty or other treatment requiring lamellar resection of the cornea at a varying depth with respect to the corneal surface. | • In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea, penetrating and/or intrastromal<br>• In lamellar IEK and corneal harvesting<br>• In the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea<br>• In the creation of a lamellar cut/resection of the cornea for lamellar IEK and for the creation of a penetrating cut/incision for penetrating IEK<br>• In patients undergoing ophthalmic surgery or other treatment requiring the creation of corneal channels for placement/insertion of a corneal inlay device |
| Beam Delivery Device | Zoom lens controls the depth of resection<br>Motorized gantry positioning<br>Electrical gantry motors lock the position of the delivery assembly<br>Magnified video image provides a view of the surgical field<br>Contact light and maximum applanation light; light that indicates increased applanation contact pressure within the acceptable range.<br>Cone illumination | None listed | Same as Subject Device |

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| | Focusing objective focuses the beam into the resection plane<br><br>Motorized mirrors and focusing objective scan the laser beam through the fixed objective to create an X-Y resection plane | | |
| Laser Type | Mode locked, diode pumped, Ytterbium-doped fiber laser | Solid state mode locked, diode pumped | Mode-locked, diode-pumped Nd:glass oscillator with a diode-pumped regenerative amplifier |
| Treatment Laser Wavelength (nm) | 1040 nm | 1020-1060nm | 1053 nm |
| Output Power, Max | 2.0 W | None listed | 0.400 W |
| Pulse Energy Range | 45-90 nJ | None listed | 300-2000 nJ |
| Maximum Pulse Energy (µJ) | 0.2 µJ | < 6 µJ | 2.5 µJ |
| Repetition Rate (MHz) | 10 MHz | < 10 MHz with ±10% tolerance | 0.15 MHz |
| Pulse Duration (fs) | 100-200 fs | 200-500 fs | 600-800 fs |
| Spot size | < 2 µm | < 2 µm | < 3 µm |
| System controls | FPGA and Microprocessors, with Graphical User Interface | None listed | Microprocessor with Graphical User Interface |
| **Patient Interface** | | | |
| Patient Contact Interface | Suction-ring type interface device | Same | Same |
| Patient Interface Usage | Single Use | Same | Same |
| Patient Contact Portion of the Device | Contact Lens – Fused Silica<br><br>Suction Ring – TPE Versaflex | None listed | Contact Lens – Same as Subject Device<br><br>Suction Ring – C – Flex |
| Sterilization Method of Disposable | Radiation (Gamma) | EO | Same as Subject Device |

| | | | |
|---|---|---|---|
| Source of Vacuum | Automatic | None listed | Manual |
| Operating System | Windows 10, Linux | None listed | QNX operating system running proprietary iFS software |
| Available Resection Patterns | The ELITA™ Laser provides a single five-part resection for flap creation (using a raster pattern with multi-layer side cut); a pocket cut is also available for management of opaque bubble layer | None listed | Surgeon can choose from the following patterns to create a flap:<br>• Spiral<br>• Raster<br>• Double Raster<br>• Side Cut Only<br>• Pocket<br>• Flap Well<br>• Flap + Oval<br>• Inlay |

## [807.92(b)(3)] Conclusion

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| **Conclusions from Non-Clinical and Clinical Tests:** | The **ELITA™** Femtosecond Laser System and **ELITA™** Patient Interface are substantially equivalent to the currently cleared FEMTO LDV™ Femtosecond Surgical Laser (specific to regulation number) and iFS Advanced Laser System (specific to intended use and technology). The subject device and its accessory have a similar intended use, indications for use, and fundamental scientific technology compared to the predicate devices. The subject devices were determined to be substantially equivalent based on successful completion of non-clinical bench testing, Electromagnetic Compatibility (EMC) testing, software and design verification and validation testing. Based on the similarities between the subject devices and the predicates, no new risks were introduced; therefore, animal and clinical testing was not required. The successful results from the aforementioned testing were obtained using well-recognized international standards including several FDA recognized consensus standards. In addition, AMO has demonstrated through risk analysis and performance testing that the subject devices are substantially equivalent and are at least as safe and effective as the predicate devices. |