June 15, 2020

Carl Zeiss Meditec AG
Katrin Faber
Regulatory Affairs Manager / MED-RAO
Goeschwitzer Strasse 51-52
Jena, 07745 DE Thuringen

Re: K193376
Trade/Device Name: Visalis V500, Visalis S500
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: April 24, 2020
Received: May 6, 2020

Dear Katrin Faber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193376

Device Name
VISALIS V500 / VISALIS S500

Indications for Use *(Describe)*

The Indication for Use is as follows:

The VISALIS V500 and VISALIS S500 Surgical System is indicated for surgical treatment of the anterior segment of the eye by performing irrigation, irrigation /suction, phacoemulsification of the crystalline lens, anterior vitrectomy and coagulation techniques using bipolar diathermy.

The VISALIS V500 is indicated for use in vitreo-retinal surgery such as retinal detachment and other pathologies of the vitreous body and the posterior segment of the human eye.

ACCESSORIES:

ULITE PHACO HANDPIECE

This active re-usable device is an accessory for ZEISS phaco systems. It has been designed to emulsify and aspirate the eye lens during human eye surgery by phacoemulsification technique.

DIATHERMY PROBES

The DIATHERMY PROBES are active re-usable device is an accessory for ZEISS phaco systems. It has been designed to cauterize (stop bleeding) small vessels during human eye surgery on the anterior segment.

ENDODIATHERMY PROBES

This active single use device is an accessory of ZEISS phaco systems with posterior segment functionality. It has been designed to cauterize (stop bleeding) small vessels in the eye bulb and/or on the retina using a high frequency electrical current (generated from the equipment to which it is connected) passed through tissue from one electrode to another.

ENDOILLUMINATION PROBES

This single use device is an accessory of ZEISS phaco systems with posterior segment functionality. It has been designed to internally illuminate the eye bulb transmitting the light emitted by a xenon lamp.

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

(per 21 CFR §807.92)

VISALIS V500 / VISALIS S500

GENERAL INFORMATION **K193376**

Manufacturer: Carl Zeiss Meditec AG
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Date prepared:	April 23, 2020
Classification Name:	Phacofragmentation system
Product Code and Class:	HQC – Class 2
Classification:	21 CFR 886.4670 / Panel: Ophthalmic
Common Name	Phacofragmentation/ Vitrectomy system
Trade/Proprietary Name:	VISALIS V500 VISALIS S500
Predicate Device	ALCON CONSTELLATION ® Vision System
Predicate 510(k)	K141065

DEVICE DESCRIPTION (21 CFR §807.92(a)(4))

The VISALIS V500 / VISALIS S500 Surgical System has been designed to be used in surgical theaters by qualified medical personnel (eye surgeon) for surgical methods of treatment of the anterior and posterior segment of the human eye. The equipment has been designed for the performance of irrigation, irrigation/suction, phacoemulsification of crystalline lens, anterior and posterior vitrectomy, bipolar diathermy coagulation techniques, air and silicone oil tamponade, endoocular illumination. The system is intended for use in clinics, hospitals or other human medicine institutions.

To perform the ophthalmic surgery a variety of accessories are available. (See Table 5-1 below).
As main accessory the ULITE PHACO HANDPIECE is necessary to perform the surgery. With this handpiece the lens is destroyed by ultrasonic. Furthermore, irrigation and aspiration is provided by the handpiece.

ZEISS decided to separate the accessories into groups as followed:

Group	**Examples**
Accessories for VISALIS V500 / VISALIS S500	Different Footswitches and Controls, Drapes and Covers
Accessories for phacoemulsification	Handpiece, Tips, Sleeves, Test Chambers, TIP Wrenches
Accessories for irrigation/aspiration	Irrigation and Aspiration (I/A) handpieces, I/A cannulas incl. sleeves, I/A Tubing sets
Accessories for diathermy and anterior vitrectomy	Diathermy Forceps, Probes to irrigate, cut and aspirate the cut vitreous material
Accessories for retinal surgery	Posterior vitrectomy probes, Trocar kits, Scleral infusion cannulas, irrigation tube sets, Endo-illumination
Accessories for endodiathermy	Endodiathermy probes

Table 5-1: Groups of Accessories

INDICATIONS FOR USE (21 CFR §807.92(a)(5))

MAIN DEVICE

The VISALIS V500 and VISALIS S500 Surgical System is indicated for surgical treatment of the anterior segment of the eye by performing irrigation, irrigation /suction, phacoemulsification of the crystalline lens, anterior vitrectomy and coagulation techniques using bipolar diathermy.

The VISALIS V500 is indicated for use in vitreo-retinal surgery such as retinal detachment and other pathologies of the vitreous body and the posterior segment of the human eye.

ACCESSORIES

ULITE PHACO HANDPIECE

This active re-usable device is an accessory for ZEISS phaco systems. It has been designed to emulsify and aspirate the eye lens during human eye surgery by phacoemulsification technique.

DIATHERMY PROBES

The DIATHERMY PROBES are active re-usable device is an accessory for ZEISS phaco systems. It has been designed to cauterize (stop bleeding) small vessels during human eye surgery on the anterior segment.

ENDODIATHERMY PROBES

This active single use device is an accessory of ZEISS phaco systems with posterior segment functionality. It has been designed to cauterize (stop bleeding) small vessels in the eye bulb and/or on the retina using a high frequency electrical current (generated from the equipment to which it is connected) passed through tissue from one electrode to another.

POSTERIOR VITRECTOMY PROBE

This active single use device is an accessory of ZEISS phaco systems with posterior segment functionality. It has been designed to cut and aspirate the vitreous humor through its cutting port during human eye surgery.

ENDOILLUMINATION PROBES

This single use device is an accessory of ZEISS phaco systems with posterior segment functionality. It has been designed to internally illuminate the eye bulb transmitting the light emitted by a xenon lamp.

RISK MANAGEMENT

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by design means, protection measures and user instructions. To confirm that the measures are effective and that the product meets its intended uses, verification of requirements and standards, and validation of the clinical workflow was performed. Carl Zeiss Meditec adheres to recognized and established industry practice and relevant international standards where indicated.

The device labeling contains instructions for use and any necessary cautions and warnings for safe and effective use of the device.

VISALIS V500 / VISALIS S500 is provided with an Instruction for Use. In this Instruction for Use the available accessory is listed.

Every accessory or accessory set is provided with a separate Instruction for Use.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

(21 CFR §807.92(a) (6))

Substantial Equivalence is demonstrated to ALCON CONSTELLATION® Vision System (K141065). This predicate has not been subject to a design-related recall.

Each ophthalmic system is designed to be used for the anterior and posterior segment of the eye. However, the ZEISS device is not yet equipped with a laser source.

Both systems are provided with various accessories, in particular with a handpiece for emulsification of the lens. A general overview is given in the following comparison table:

Criteria	**VISALIS V500 / VISALIS S500**	**ALCON CONSTELLATION ® Vision System**
Design Aspects		
Hardware	- Illumination - Irrigation / Aspiration - Vitrectomy - Diathermy - Ultrasound - Air tamponate - Silicone tamponade	- Illumination - Irrigation / Aspiration - Vitrectomy - Diathermy - Ultrasound - Air tamponate - Silicone tamponade - Laser

Irrigation		
Liquid supply:	- Gravity irrigation - Controlled irrigation - Combined irrigation	- Pressurized Infusion only

Criteria	VISALIS V500 / VISALIS S500	ALCON CONSTELLATION ® Vision System
Aspiration		
Types of aspiration pumps:	Peristaltic and Venturi pump	Perestaltic pump

Phacoemulsification		
Type of handpiece:	piezoelectrical	piezoelectrical

Diath (Diathermy)		
Operating frequency:	2 MHz (± 20 %)	1.5 Mhz ± 10%.

Vit (Vitrectomy)		
Cutting mode:	Back-and-forth Single cut mode available	3D, Momentary, PropVac, VitWet Single cut mode available

Scissors		
Cutting mode:	Horizontal scissors	Proportional, Multi-Cut

Air infusion		
Pressure source:	integral rotary vane compressor	From external source
Silicone oil injection		
Pressure source:	Compressed air from external source	From external source

Illumination		
Type:	Two independent light sources	One light source
Color temperature:	Lamp 1: 4300 K Lamp 2: 5000 K	Just one color temperature
Filters:	Green filter, retina protection filter (blue barrier filter)	Fixed UV and IR filters
Safety filter:	IR-UV-blocking filter	Fixed UV and IR filters

Table 5-2: General Comparison Table

Evaluation performed on the VISALIS V500 / VISALIS S500 supports the indications for use statement and demonstrates that the device is substantially equivalent to the predicate device and does not raise new questions regarding safety and effectiveness.

SUMMARY OF PERFORMANCE DATA (21 CFR §807.92(B))

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

- **ISO 14971:2007** is a general standard with no specific test acceptance criteria. This standard was used to demonstrate compliance with risk management processes and to support ANSI/AAMI ES60601-1 and IEC 60601-1-2.

- **ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012**
  Basic safety and essential performance has been evaluated for the VISALIS V500 / VISALIS S500. VISALIS V500 / VISALIS S500 has been found to be in compliance with the ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 standard.

  IEC 60601-1-2:2014
  Electromagnetic compatibility (EMC) has been evaluated for VISALIS V500 / VISALIS S500. VISALIS V500 / VISALIS S500 has been found to be in compliance with the IEC 60601-1-2:2007 standard.

- **IEC 60601-2-2:2017**
  The particular requirements for high frequency surgical equipment and high frequency accessories were evaluated for VISALIS V500 / VISALIS S500 and applicable accessories. VISALIS V500 / VISALIS S500 as well as the applicable accessories has been found to be in compliance with the IEC 60601-2-2:2017 standard.

- **IEC 80601-2-58:2008**
  IEC 80601-2-58, applicable for lens removal devices and vitrectomy devices has been evaluated for the VISALIS V500 / VISALIS S500 and applicable accessories. The VISALIS V500 / VISALIS S500 has been found to be in compliance with the IEC 80601-2-58 standard.

- **IEC 62304:2006/A1:2015**
  The Software for the VISALIS V500 / VISALIS S500 was documented and tested according to IEC 62304. Details can be found under Section 16 of this submission. The device and its software has been found to be in compliance with IEC 62304 standard.

- **IEC 62366-1:2015**
  IEC 62366 is a general standard with no specific test acceptance criteria. This standard was used to demonstrate compliance with the usability requirements of the VISALIS V500 / VISALIS S500 and its accessories.

- **IEC 15752:2010**
  IEC 15752, applicable for the endoilluminators and that optical radiation safety has been evaluated for the VISALIS V500 / VISALIS S500 and applicable accessories. The VISALIS V500 / VISALIS S500 as well as the applicable accessories has been found to be in compliance with the IEC 15752 standard.

Biocompatibility evaluations of materials coming in contact with the patient or patient fluid path have been performed to the following standards:

- **ISO 10993-1:2009**
  ISO 10993-1:2009, applicable for the accessories coming in contact with the patient has been evaluated. The applicable accessories have been found to be in compliance with the ISO 10993-1 standard.

- **ISO 10993-5:2009**
  ISO 10993-5:2009, applicable for the accessories coming in contact with the patient has been evaluated. The applicable accessories have been found to be in compliance with the ISO 10993-5 standard.

- **ISO 10993-10:2010**
  ISO 10993-10:2009, applicable for the accessories coming in contact with the patient has been evaluated. The applicable accessories have been found to be in compliance with the ISO 10993-10 standard.

- **ST72:2011/(R)2016**
  ST72, applicable for the accessories coming in contact with the patient has been evaluated. The applicable accessories have been found to be in compliance with the ST72 standard.

- **ISO 17665-1:2006**
  ISO 17665-1, applicable for re-processable accessories has been evaluated. The applicable accessories have been found to be in compliance with the ISO 17665-1 standard.

- **ISO 11135: 2014**
  ISO 11135, applicable for ETO sterilized accessories has been evaluated. The applicable accessories have been found to be in compliance with the ISO 11135 standard.

- **ISO 10993-7:2008-10**
  ISO 10993-7, applicable for ETO sterilized accessories has been evaluated. The applicable accessories have been found to be in compliance with the ISO 10993-7 standard.

- **ISO 11737-2:2009**
  ISO 11737-2, applicable for sterilized accessories has been evaluated. The applicable accessories have been found to be in compliance with the ISO 11737-2 standard.

- **F88/F88M-15**
  F88/F88M-15, applicable for sterilized accessories has been evaluated. The applicable accessories have been found to be in compliance with the F88/F88M standard.

- **F1929-2015**
  F1929, applicable for sterilized accessories has been evaluated. The applicable accessories have been found to be in compliance with the F1929 standard.

Conclusion

The non-clinical data support the safety of the device and the hardware verification and validation demonstrate that the VISALIS V500 / VISALIS S500 should perform as intended in the specified use conditions.

The data demonstrate that the VISALIS V500 / VISALIS S500 performs comparably to the predicate device that is currently marketed for the same intended use.

SUBSTANTIAL EQUIVALENCE TO PREDICATE (21 CFR §807.92(B)(1))

As previously indicated VISALIS V500 / VISALIS S500 has been tested to meet the product requirements and is considered to be substantially equivalent to the predicate as indicated above.

SUMMARY (21 CFR §807.92(C))

In summary, based on the successful verification and validation testing, it is Carl Zeiss Meditec AG's opinion that VISALIS V500 / VISALIS S500 does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate device.

Additionally, all testing deemed necessary was conducted on VISALIS V500 / VISALIS S500 to ensure that the device is as safe and effective when used in accordance with its Instructions for Use as the predicate device.