January 21, 2026

Digital Surgery Systems, Inc. (D.B.A True Digital Surgery)
Lu Ju
Regulatory Affairs Specialist
125 Cremona Dr
Suite 110
Goleta, California 93117

Re: K251286
Trade/Device Name: Affirm 400
Regulation Number: 21 CFR 882.4950
Regulation Name: Diagnostic Neurosurgical Microscope Filter
Regulatory Class: Class II
Product Code: QFX
Dated: December 17, 2025
Received: December 22, 2025

Dear Lu Ju:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JULIA E. SLOCOMB -S Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.01.21 10:19:48 -05'00'

for Jaime Raben, Ph.D.
Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251286

Device Name
Affirm 400

Indications for Use *(Describe)*
Affirm 400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III and IV gliomas during neurosurgery, comprising an excitation filter for blue spectral range between 390 nm and 420 nm and an observation filter for visible light with spectral range between 510 nm and 700 nm.

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.

510(k) SUMMARY

1. SUBMITTER

OWNER/SUBMITTER:	True Digital Surgery 125 Cremona Drive, Suite #110 Goleta, CA 93117
PRIMARY CONTACT:	Lu Ju 805-978-5400 (phone) lju@truedigitalsurgery.com
SECONDARY CONTACT:	Deanna Najman dnajman@truedigitalsurgery.com
DATE:	1/19/2026

2. DEVICE

DEVICE TRADE NAME:	Affirm 400
DEVICE CLASS:	Class II
CLASSIFICATION NAME:	Diagnostic Neurosurgical Microscope Filter
REGULATION NUMBER:	882.4950
PRODUCT CODE:	QFX

3. PREDICATE DEVICE

PREDICATE DEVICE:	BLUE 400 (K211346) from Carl Zeiss Meditec AG
DEVICE CLASS:	Class II
CLASSIFICATION NAME:	Diagnostic Neurosurgical Microscope Filter
REGULATION NUMBER:	882.4950
PRODUCT CODE:	QFX

4. DEVICE DESCRIPTION

Affirm 400 is an accessory to the Class I Digital Surgical Microscope (DSM). Affirm 400 is a hardware and software which allows intraoperative viewing of suspected grade III and IV gliomas under fluorescence with the 5-ALA optical imaging agent. Affirm 400 is composed of optical filters: the "Excitation" filter and the "Emission" filter. The Excitation filter is designed to filter light between 390-

420 nanometers. The Emission filter is designed to filter light between 510 – 700 nanometers. The use of a suitable detection system allows for visualization of surgical interventions. The emitted light is then captured by the optics of the digital microscope, passed through filters to remove unwanted wavelengths of light, and finally detected by the image sensors. This detected signal is then projected on a monitor enabling the surgeon to view the magnified image. The Affirm 400 includes installation of a software license that facilitates use of the accessory. After the software license is installed, the user has the option to switch from the normal white light mode of the surgical microscope to the Affirm 400 mode.

5. INDICATIONS FOR USE

Affirm 400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III and IV gliomas during neurosurgery, comprising an excitation filter for blue spectral range between 390 nm and 420 nm and an observation filter for visible light with spectral range between 510 nm and 700 nm.

6. SUBSTANTIAL EQUIVALENCE

	Subject Device - True Digital Surgery Affirm 400	**Predicate Device – Carl Zeiss Meditec, AG BLUE 400**	**Substantial Equivalence Discussion**
Submission#	K251286	K211346	
Product Code	QFX	QFX	Identical
Regulation number	882.4950	882.4950	Identical
Regulation Medical Specialty	Neurology	Neurology	Identical
Class No.	II	II	Identical
Device Description	Accessory to the microscope (Filter)	Accessory to the microscope (Filter)	Identical
Intended Use	Patients undergoing neurological procedures.	Patients undergoing neurological procedures.	Identical
Indications for Use	- Affirm 400 is a surgical microscope accessory used in fluorescent visualization of suspected grade III and IV gliomas during neurosurgery, comprising an excitation filter for blue spectral range between 390 nm and 420 nm and an observation filter for visible light with spectral range between 510 nm and 700 nm.	BLUE 400 is an accessory of the surgical microscope and allows the fluorescence observation of fluorophores with an excitation peak between 400 nm and 410 nm and the fluorescence emission observation comprising the spectrum in a spectral band of 620 - 710 nm. The ZEISS BLUE 400 is a surgical microscope accessory used in fluorescent	Similar

		visualization of suspected grade III and IV gliomas during neurosurgery.	
Fluorescent Agent	5-ALA	5-ALA	Identical
Visualization Result	Fluorescent image of distribution of the accumulated protoporphyrin IX (PpIX) in malignant tissue during operation.	Fluorescent image of distribution of the accumulated protoporphyrin IX (PpIX) in malignant tissue during operation.	Identical
Visualization of Real-time Images	Yes	Yes	Identical
Fluorescence Excitation Spectral Window	390 nm – 420 nm	400 nm – 430 nm	Equivalent for fluorescence agent
Spectrum of the Emission Filter	510 – 700 nm	430 – 800 nm	Equivalent for detecting the fluorescence agent
Combination Device	No	No	Identical
Light Specifications - Type	VIS-UV LED Blue light – Fluorescence	Xenon lamp White Light – Fluorescence	Different
Test Card	Pre-operative check test card	Pre-operative check test card	Identical

7. SUMMARY OF PERFORMANCE TESTING

Affirm 400 has been tested to meet the product requirements and software requirements. The following performance testing was conducted to further demonstrate substantial equivalence to the predicate device.

Bench Testing

Non-clinical performance testing was completed to evaluate the performance of the microscope system relevant to each of the Affirm 400 product requirements. The functional and system level testing showed that the system met the defined specifications.

Side by side performance testing including color visualization testing was completed with the predicate device. Special controls were addressed via additional testing or product verification. The following testing has been conducted with and without cover glass to address the special controls.

Special Control	Testing or verification Summary	Results
Spectrum of the Illumination Source	Spectrum of the illumination source (400-410nm) was assessed using a spectrometer before the application of the excitation filter module. The obtained results were compared to the predicate device	Pass

Maximum Power and Irradiance of the Illumination Source	Maximum power was measured in the final product configuration of the subject device which has the excitation filter permanently installed in front of the illumination source. The maximum power obtained after the application of the excitation filter module was compared to the predicate device with the excitation filter module applied.	Pass
Irradiance Spectrum of the Excitation Light and Spectral Response of the Excitation Filter	After passing through the excitation filter module, the illumination light's irradiance spectrum (390-420nm) was measured at the maximum working distance (450mm) with a spectrometer. The irradiance spectrum of the subject device was compared to the predicate device.	Pass
Maximum Excitation Power and Power Density	The maximum power (mW) and power density (mW/cm^2) was measured at the minimum working distance (200mm) and maximum working distance (450mm) using a power meter. These measurements of the subject device were compared to the predicate device.	Pass
Optical Path Loss	The optical path loss measurement does not apply for our digital surgical microscope due to differences in its optical design compared to the predicate device. Instead, intensity contrast measurements were performed to verify that the image quality is adequate for effectively differentiating objects in the image.	Pass
Spectrum of the Emission Filter	The spectrum of the emission filter was verified by visual inspection of lot release transmission data. The spectrum of the subject device was compared to the predicate device	Pass
Homogeneity of the Excitation Light at the Focal Point	A uniform flat white surface positioned at a minimum working distance (200mm) was imaged using Affirm 400 module. The decrease of intensities from the center of the focal plane to the corners were evaluated. The homogeneity of the excitation light of the subject device was compared to the predicate device	Pass
Fluorescence detection sensitivity	Fluorescent phantoms were developed in a range of fluorescing agent concentrations and a range of intervening tissue depths. These phantoms were then imaged using the predicate device and subject device.	Pass
Pre-Operative Phantom Test	This test was conducted to demonstrate that the Affirm 400 test card is suitable for the preoperative checks of a surgical microscope camera. The phantom has one fluorescent area and was imaged by the surgical microscope camera.	Pass
Spectral Sensitivity of Camera	The cross talk measurement in addition to analysis of camera sensitivity plots demonstrate that camera adequately performs visualizing tumor fluorescence in the correct detection channels (r/g/b) to avoid false positives/false negatives.	Pass

Software Verification and Validation Testing
Software verification and validation (V&V) testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions." The software for this device was considered as enhanced documentation level, since a failure or latent flaw of the device software function(s), such as inadequate quality of displayed images, would potentially present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

Sterilization and Shelf Life
The device is provided non-sterile. Cleaning instructions are provided in the system user manual that direct users to follow the cleaning procedures of the surgical operating microscope that the Affirm 400 is installed in.

Shelf-Life is not applicable.

Biocompatibility
The device does not have patient-contacting materials; therefore, a biocompatibility assessment is not needed for this device.

8. CONCLUSION

The indications for use of the subject device, Affirm 400, are equivalent to the indications for use of the predicate device BLUE 400. The technological characteristics and risk profile of the subject device is similar to the predicate device. Based on the similarities of the indications for use, technological characteristics, and the results of the non-clinical performance testing, the Affirm 400 device is substantially equivalent to the legally marked predicate device, BLUE 400.