June 27, 2025

Digital Surgery Systems, Inc. (d.b.a True Digital Surgery)
Lu Ju
Regulatory Affairs Specialist
125 Cremona Dr Suite 110
Goleta, California 93117

Re: K243077
Trade/Device Name: Affirm 800
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-Ray System
Regulatory Class: Class II
Product Code: IZI
Dated: May 27, 2025
Received: September 30, 2024

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2025.06.27 12:14:55 -04'00'

Adam D. Pierce, Ph.D.
Assistant 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)*
K243077

Device Name
Affirm 800

Indications for Use *(Describe)*
The Affirm 800 is used in viewing intra-operative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral vessel branch occlusion, as well as intraoperative blood flow and vessel patency in bypass surgical procedures in neurosurgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 ext. 181 (phone) lju@truedigitalsurgery.com
SECONDARY CONTACT:	Deanna Najman dnajman@truedigitalsurgery.com

DATE:	June 25th, 2025

2. DEVICE

DEVICE TRADE NAME:	Affirm 800
DEVICE CLASS:	Class II
CLASSIFICATION NAME:	System, X-Ray, Angiographic
REGULATION NUMBER:	892.1600
PRODUCT CODE:	IZI

3. PREDICATE DEVICE

PREDICATE DEVICE:	DIR 800 (K202391) from Aesculap
DEVICE CLASS:	Class II
CLASSIFICATION NAME:	System, X-Ray, Angiographic
REGULATION NUMBER:	892.1600
PRODUCT CODE:	IZI

4. DEVICE DESCRIPTION

The Affirm 800 module is designed to work in conjunction with the Class I Digital Surgical Microscope (DSM) RE3. The Affirm 800 module, a Class II device, comprises hardware and software components that enable the Digital Surgical Microscope to emit excitation light in specific wavelengths to activate the fluorescence properties of Indocyanine Green (ICG). The fluorescence signal emitted by the patient represents the distribution of the infrared dye in the patient's blood vessels during surgery. 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 3D monitor, which is part of the microscope system, enabling the surgeon to view the magnified image.

The integrated Affirm 800 fluorescence module is used to visualize infrared fluorescent areas in the surgical field and includes features to record and play back a video clip of the area of focus where fluorescent light is emitted. The module has been designed for excitation in the wavelength range from 740 nm to 800 nm and for fluorescence visualization in the wavelength range from 820 nm to 900 nm. The fluorescence feature generates an image in the infrared spectrum, which means it cannot be seen by the naked eye.

5. INDICATIONS FOR USE

The Affirm 800 is used in viewing intra-operative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral vessel branch occlusion, as well as intraoperative blood flow and vessel patency in bypass surgical procedures in neurosurgery.

6. SUMMARY/COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Affirm 800 and its predicate device have the same intended use, and same design principles, identical materials, and similar technological characteristics. The technology used in the subject and predicate devices to illuminate the area of interest, optically focus the emitted light, filter unwanted wavelengths of light, and capture the light on the image sensor are identical. The software used to display the image on screen, as well as record and play back video is likewise similar.

The Affirm 800 and predicate device each utilize a surgical stereo microscope imaging system and have identical functions for viewing, recording, and replaying fluorescent images. Identical cameras are utilized as sensors and the infrared options are equivalent. Each device utilizes the same type of fluorescent agent, Indocyanine Green (ICG), to visualize blood flow. Using near infrared excitation, real-time visualization of images takes place in identical transmission ranges.

	Subject Device - True Digital Surgery Affirm 800	Predicate Device - Aesculap DIR 800	Substantial Equivalence Discussion
Submission#	K243077	K202391	
Product Code	IZI	IZI	Identical
Regulation number	892.1600	892.1600	Identical
Class No.	II	II	Identical
Indications for Use	The Affirm 800 is used in viewing intra-operative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral vessel branch occlusion, as well as intraoperative blood flow and vessel patency in bypass surgical procedures in neurosurgery.	The DIR 800 is an accessory for the Aesculap Aeos and is used in viewing intra-operative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency in neurosurgery. It also aids in the visual assessment of intraoperative blood flow and vessel patency in bypass surgical procedures in neurosurgery.	Similar
Basic System Function	View, record, and replay fluorescent images of blood vessels in the cerebral area, view blood flow and vessel patency in bypass surgical procedures during neurosurgery.	View, record, and replay fluorescent images of blood vessels in the cerebral area, and view blood flow and vessel patency in bypass surgical procedures during neurosurgery.	Identical
Fluorescent Agent	Indocyanine Green (ICG)	Indocyanine Green (ICG)	Identical
Visualization of Real-time Images	Yes	Yes	Identical
Display	Video and images are presented on 3D monitor. Picture-in-picture available.	Video and images are presented on 3D monitor. Picture-in-picture available.	Same
Light Source	2x white light LEDs and 13x IR LEDs	2x white light LEDs and 13x IR LEDs	Identical
White Light Application	400 nm – 700 nm	400 nm – 700 nm	Identical

	Subject Device - True Digital Surgery Affirm 800	**Predicate Device - Aesculap DIR 800**	**Substantial Equivalence Discussion**
ICG Excitation	740 nm – 800 nm bandpass filter	740 nm – 800 nm bandpass filter	Identical
ICG Detection	Filter with high transmission from 820 nm – 900 nm	Filter with high transmission from 820 nm – 900 nm	Identical
Test Card	Pre-operative check test card	Pre-operative check test card	Same
Distance of Imaging Head to Patient	200 mm – 300 mm	200 mm – 300 mm	Same
Camera adaptation	Integrated into the microscope head	Integrated into the microscope head	Same
Zoom	Motorized 8.9:1	Motorized 8.9:1	Same
Auto detection of fluorescence influx	Yes	Yes	Same
Autofocus	Yes	Yes	Same
Color map	Yes	No	Different

7. SUMMARY OF PERFORMANCE TESTING

Design verification testing was performed to ensure that the subject device meets functional requirements, including design specifications, and to demonstrate that its performance is substantially equivalent to the predicate.

Test	Test Method	Results
Image Quality (3D display and 3D glasses)	Characterize and confirm equivalent performance of the subject device compared to the predicate for the following: *1. Sensitivity to NIR fluorescence in terms of ICG Molar concentration:* - Weber contrast - Signal to Noise Ratio - Fluorescence Pixel Intensity for each concentration - Limit of detection - Limit of quantification - Signal linearity between limit of quantification and at least 3.2 micromolar concentration. *2. Spatial and Temporal Noise* - Spatial noise as measured from the image pipeline - Temporal noise measured using 30 black frames *3. Left and Right Eye Comparison* *4. Sensitivity to NIR fluorescence in terms of depth penetration* - Weber Contrast - Signal-to-Noise Ratio 5. *Stereoscopic Crosstalk* - Stereoscopic Extinction Ratio - Stereoscopic Crosstalk	Pass

	6. An animal study was conducted using 5 porcine models with a clinically relevant ICG dose. Surgeons evaluated image quality on a scale of 1 to 5, where 1 represented poor image quality and 5 represented very good quality, in visualizing vessels of various sizes. The study assessed image quality using a 3D display (part of the Class I surgical microscope) and 3D glasses.	

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 an enhanced documentation level, since in fluorescing modes, a failure or flaw of the imaging subsystem software could indirectly present a hazardous situation with a risk of death or serious injury to a patient prior to the implementation of risk control measures.

8. CONCLUSION

The indications for use of the subject device, Affirm 800, are equivalent to the indications for use of the predicate device, DIR 800. The technological characteristics and risk profile of the subject device are similar to those of the predicate device. Based on the similarities of the indications for use, technological, and design verification test results, the subject device is determined to be substantially equivalent to Aesculap's DIR 800 predicate device.