January 21, 2021

Aesculap, Inc.
Ms. Kathy A. Racosky
Project Manager I
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K202391
Trade/Device Name: DIR 800
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic X-ray system
Regulatory Class: Class II
Product Code: IZI
Dated: August 21, 2020
Received: August 21, 2020

Dear Ms. Racosky:

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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K202391

Device Name
DIR 800

Indications for Use *(Describe)*
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.

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 (as required by 21 CFR 807.92)**

***DIR 800***
January 21, 2021

**COMPANY:** Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

**CONTACT:** Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com

**TRADE NAME:** DIR 800

**COMMON NAME**: Angiographic x-ray system

**CLASSIFICATION:** Class II

**CLASSIFICATION NAME:** System, X-Ray, Angiographic

**REGULATION NUMBER:** 892.1600

**PRODUCT CODE:** IZI

## SUBSTANTIAL EQUIVALENCE

DIR 800 is substantially equivalent to Carl Zeiss Surgical GmbH, INFRARED 800 with FLOW Option (K100468). DIR 800 has similar indications for use and is similar in design and operating principle to the predicate device.

## INDICATIONS FOR USE

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.

## DEVICE DESCRIPTION

The DIR 800 is an accessory to the Aeos Digital Surgical Microscope Class I 510(k) exempt surgical operating microscope. The DIR 800 allows the Aeos to produce excitation light to illuminate the fluorescence properties of the Indocyanine Green (ICG). The generated fluorescence signal depicts the distribution of the infrared dye in the patient's blood vessels during surgery.

**TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))**

As established in this submission, the DIR 800 is substantially equivalent to other predicate devices cleared by FDA. The subject device is shown to be substantially equivalent and has the same technological characteristics to its predicate device through comparison in function, design and intended use. The device characteristics comparing the DIR 800 to the predicate device are summarized below.

The subject and predicate device each utilizes a surgical stereo microscope imaging system and has the same basic functions for viewing, recording, and replaying fluorescent images. Similar 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 infared excitation, real-time visualization of images takes place in equivalent transmission ranges.

The indications for use for DIR 800 are similar to the indications for use for the predicate device cited in this file. A technological comparison and testing demonstrate that the DIR 800 is functionally equivalent to the predicate device. An evaluation performed on the DIR 800 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. Review of the comparison table below shows that the DIR 800 has similar characteristics compared to the predicate and supports the substantial equivalence determination.

| | **Aesculap, Inc.**<br>**DIR 800** | **Predicate**<br>**Carl Zeiss Meditec AG**<br>**INFRARED 800 with FLOW 800 option** |
|---|---|---|
| **K#** | Pending | K100468 |
| **Indications** | 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. | The Carl Zeiss Surgical INFRARED 800 with the FLOW 800 option is a surgical microscope accessory used in viewing and visual assessment of intraoperative blood flow in the cerebral vascular area including, but not limited to, assessing cerebral aneurysm and vessel branch occlusion, as well as patency of very small perforating vessels. It also aids in the realtime visualization of blood flow and visual assessment of vessel types before and after Arteriovenous Malformation (AVM) surgery. Likewise, INFRARED 800 with the FLOW 800 option used during fluorescence guided surgery aids in the visual assessment of intraoperative blood flow as well as vessel patency in bypass surgical procedures in neurosurgery, plastic and reconstructive procedures and coronary artery bypass graft surgery. |

| | | |
|---|---|---|
| **Regulation number** | 892.1600 | 892.1600 |
| **Product code** | IZI | IZI |
| **Regulation Medical Specialty** | Radiology | Radiology |
| **Device Description** | Accessory to surgical stereo microscope for intraoperative imaging. | Accessory to surgical stereo microscope for intraoperative imaging. |
| **Basic System Function** | 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. | View, record, and replay fluorescent images of blood vessels in the cerebral area, view bypass grafts during coronary artery bypass (CABG) surgery, and view blood flow during plastic and reconstructive surgery. |
| **Accessory to** | The DIR 800 is an accessory to the Aesculap Aeos [Class I Exempt] | INFRARED 800 is an accessory to the OPMI Pentero surgical microscope. [Class I Exempt]<br>FLOW 800 is an accessory to INFRARED 800. |
| **Sensor** | CMOS video camera, infrared-sensitive | CCD video camera<br>Infrared-sensitive video camera<br>Black & white camera |
| **Fluorescent Agent** | Indocyanine Green (ICG) | Indocyanine Green (ICG) |
| **Activation of the ICG option** | The press of a single button on the surgical microscope activates the ICG function. | The press of a single button on the surgical microscope activates the ICG function. |
| **Result** | Fluorescent image of the distribution of the infrared dye in the patient's blood vessels during the operation. | Fluorescent image of the distribution of the infrared dye in the patient's blood vessels during the operation.<br>FLOW 800 provides overview and comparison functions of display and a summary of the dynamic of the fluorescent dye. |
| **Visualization of Real-time Images** | Yes | Yes |
| **Display** | Video and images are presented on monitor. Picture-in-picture available. | Video and images are presented on monitor. Image may also be displayed in the eyepiece. Picture-in-picture available. |
| **Termination of the ICG option** | Determined by surgeon or will turn off automatically after 100 seconds. | Determined by surgeon or will turn off automatically after 5 minutes. |
| **Light Source** | 2x white light LEDs and 13x IR LEDs | 2x 300W Xenon lamps |
| **White Light Application** | 400 nm – 700 nm | 400 nm – 700 nm |
| **ICG Excitation** | 740 nm – 800 nm bandpass filter | 700 nm – 780 nm bandpass filter |
| **ICG Detection** | Filter with high transmission from 820 nm – 900 nm | Filter with high transmission from 820 nm – 900 nm |
| **Test Card** | Pre-operative check test card | Pre-operative check test card |
| **Distance of Imaging Head to Patient** | 200 mm – 300 mm | 200 mm – 500 mm |
| **Camera adaptation** | Integrated into the microscope head | Integrated into the microscope head |
| **Zoom** | Motorized 8.9:1 | Motorized 6:1 |
| **Auto detection of fluorescence influx** | Yes | Yes |
| **Autofocus** | Yes | Yes |
| **Control System** | Personal Computer | Personal Computer |
| **Storage** | HDD | HDD, DVD |

## PERFORMANCE DATA

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

### Bench testing

The following bench testing was performed to demonstrate that the DIR 800 performs as intended and is substantially equivalent to the predicate device.

| Test | Test Summary | Results |
|---|---|---|
| Verification that the reference target fluoresces | No fluorescence is detected by the Aeos when DIR 800 mode is disabled | Pass |
| Verification of the software / hardware accessory visualization feature | The excitation light bandwidth and peak fall within 700nm-802nm range at all working distances | Pass |
| | Total excitation absorption power over the entire ICG excitation spectrum | Pass |
| | Visualization of the Aeos DIR 800 mode | Pass |
| | Fluorescence pixel intensity shows the optics and detectors adequately visualize a fluorescent agent | Pass |

### Biocompatibility

None of the components come into contact with a patient; therefore, no biocompatibility data is required.

### Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Aeos System. The DIR 800 module was tested as part of the Aeos System. The system complies with the IEC 60601-1, and IEC 60601-2 standards for safety and the IEC 60601-1-2 standard 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.

### Animal Study

Animal studies using a porcine model and a rabbit model were conducted to confirm the DIR 800 enabled viewing of intra-operative blood flow in the cerebrovascular area. Testing was completed by Neurosurgeons using test cases and independent scoring assessments which were predefined in the protocol. Comparative image sets of the same cerebrovascular anatomy in either a non-occluded (before clipping), occluded (clipped) and non-occluded (after removal of clip) were visualized by the DIR 800 and digital subtraction angiography (DSA).

Data was collected using Indocyanine Green (ICG) introduced into the vascular system of a porcine model and a rabbit elastase model. Evidence regarding the capability to visualize blood flow, vascular structures and aneurysms was collected and compared directly to data collected with a DSA on the same porcine and rabbit elastase model.

The device performance was evaluated for overall image quality, brightness and illumination, visual acuity, visual artifacts, depth perception, contrast and alignment of visible light images versus fluorescent images.

The testing confirmed that the DIR 800 reflects the intended use and provides intraoperative visualization and visual assessment of blood flow when compared to the DSA. The individual assessments of comparative images verify that the DIR 800 allowed visualization of intra-operative blood flow in the cerebrovascular area and imaging of aneurysms in small sized vessels in an equivalent manner to the DSA.

The individual assessments of comparative images to verify the device performance met their pre-established acceptance criteria.

**CONCLUSION**

The subject device and predicate device have the same intended use, for viewing internal surgical sites during general surgical procedures. The specifications and functionality of the subject device is similar to the predicate device. Any differences between the devices do not raise new questions of safety and effectiveness. Performance data demonstrated that the device meets its specifications and intended uses and support the safety of the device. The hardware and software verification and validation demonstrate that the DIR 800 should perform as intended in the specified use conditions. Therefore, the subject device can be found substantially equivalent to the Carl Zeiss Surgical INFRARED 800 with the FLOW 800 option as cleared in K100468.