March 25, 2024

Synaptive Medical Inc.
Tahmina Afzali
Senior Regulatory Affairs Specialist
555 Richmond St West, Suite 800
Toronto, ON, M5V 3B1
Canada

Re: K231986
Trade/Device Name: Modus IR
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: IZI
Dated: February 22, 2024
Received: February 23, 2024

Dear Tahmina Afzali:

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.

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: 2024.03.25 17:09:27 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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)*
K231986

Device Name
Modus IR

Indications for Use *(Describe)*

Modus IR used with the Synaptive Surgical Exoscope is indicated for fluorescence imaging in conjunction with indocyanine green to aid in the visualization of vessels (micro- and macro-vasculature) and blood flow in the cerebrovasculature before, during, and after neurosurgery, plastic, and reconstructive surgeries.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The 510(k) Summary for Modus IR is provided below in accordance with 21 CFR 807.92.

I. Submitter

Applicant Name:	Synaptive Medical Inc.
Address:	555 Richmond St West, Suite 800 Toronto ON Canada M5V 3B1
Applicant Contact:	Tahmina Afzali
Contact Telephone:	647-925-3435
Contact Email:	tahmina.afzali@synaptivemedical.com
Secondary Contact:	Matthis Hamy Senior Manager, Regulatory Affairs 647-243-3333 Matthis.hamy@synaptivemedical.com
Date Prepared	March 18, 2024

II. Device Name

Device Trade Name:	Modus IR
Common Name:	Angiographic x-ray system
Classification Name:	System, X-Ray, Angiographic
Regulation Number:	21 CFR 892.1600
Regulatory Class:	II
Product Code:	IZI

III. Legally Marketed Predicate Device

Predicate Device:	INFRARED 800 with FLOW 800 option

510(k) Number	K100468
Classification Name:	System, X-Ray, Angiographic
Regulation Number:	21 CFR 892.1600
Regulatory Class:	II
Product Code:	IZI

IV. Device Description Summary

Modus IR is an accessory of the Synaptive surgical exoscope. Modus IR provides surgical staff with a means to visualize vessels and blood flow during surgical procedures that may not be visible under white light conditions. When used with the appropriate imaging agent, light output at a specific wavelength excites the imaging agent, which emits light at a specific wavelength that is detected by the optical system, thereby allowing the user to differentiate the structure that the imaging agent has concentrated in. The imaging agent is not packaged or sold as part of Modus IR. It is the responsibility of the user to source and administer the applicable imaging agent according to the excitation and observation wavelengths of Modus IR. Modus IR is selectively enabled by authorized personnel using software configuration management.

V. Indication for Use

Modus IR used with the Synaptive Surgical Exoscope is indicated for fluorescence imaging in conjunction with indocyanine green to aid in the visualization of vessels (micro- and macro-vasculature) and blood flow in the cerebrovasculature before, during, and after neurosurgery, plastic, and reconstructive surgeries.

VI. Comparison of Technological Characteristics with the Predicate Device

Modus IR is substantially equivalent to INFRARED 800 with FLOW 800 option. Modus IR shares the same fundamental technology characteristics, including principles of operation and mechanism of action as the predicate device, as shown in the Table 1 below. In both devices, the patient is exposed to the light emitted from the light source to illuminate the surgical field as part of intended operation, and visualization of a real time image is provided. For Modus IR, the video feed from the CMOS cameras are exclusively displayed on a primary monitor and optionally a second monitor. For the predicate device, CCD cameras are utilized as sensors and video and images are presented on a monitor. Modus IR provides greater optical zoom and the addition of digital zoom capabilities compared to the predicate device.

Modus IR and the predicate devices produce light to illuminate the same fluorescence agent Indocyanine Green (ICG) and visualize the emitted fluorescent signal from the distribution of the fluorescence agent in the patient's blood vessels during the operation. Modus IR and INFRARED 800 with FLOW 800 have slightly different excitation and detection wavelength ranges. However, both devices excite Indocyanine Green (ICG) before its peak absorption at 805 nm, with Modus IR's excitation range (748 - 802 nm) being closer to the peak compared to the predicate's excitation range (700 - 780 nm). They also detect emissions in nearly identical ranges (820 - 1000 nm for Modus IR and 820 – 900 nm for the predicate), with Modus IR having a slightly higher upper limit. Overall, Modus IR's excitation and emission wavelengths fall within the specifications of the fluorophore.

Table 1. Subject and Predicate Devices Technological Characteristics

	Predicate Device **Carl Zeiss** **INFRARED 800 with the FLOW 800 option**	**Subject Device** **Synaptive Medical Inc.** **Modus IR**
Basic Function	INFRARED 800 with the FLOW 800 option is an accessory to the OPMI Pentero surgical microscope for visualizing blood flow intraoperatively. FLOW 800 provides the surgeon with a processing mode that allows convenient handling and visualization of the INFRARED 800 video data.	Modus IR is an accessory to the Synaptive surgical exoscope for visualizing vessels and blood flow during surgical procedures.
Indication for Use	The Carl Zeiss Surgical INFRARED 800 with the FLOW 800 option is a surgical microscope accessory used in viewing and visual assessment of 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 of very small perforating vessels. It also aids in the real-time 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 intra-operative blood flow as well as vessel patency in bypass surgical procedures in neurosurgery, plastic and reconstructive procedures and coronary artery bypass graft surgery.	Modus IR used with the Synaptive Surgical Exoscope is indicated for fluorescence imaging in conjunction with indocyanine green to aid in the visualization of vessels (micro- and macro-vasculature) and blood flow in the cerebrovasculature before, during, and after neurosurgery, plastic, and reconstructive surgeries.

	Predicate Device **Carl Zeiss** **INFRARED 800 with the FLOW 800 option**	**Subject Device** **Synaptive Medical Inc.** **Modus IR**
Energy used and/or delivered	The patient is exposed to the light emitted from the light source to illuminate the surgical field, as part of intended operation.	The patient is exposed to the light emitted from the light source to illuminate the surgical field as part of intended operation.
Sensor	CCD video camera. Infrared- sensitive video camera, black & white camera. Standard Definition resolution (720 x 480)	CMOS video camera with sensors for white light and Infrared High-Definition resolution (1920 x 1080)
Fluorescence Agent	Indocyanine Green (ICG)	Indocyanine Green (ICG)
Activation of Fluorescent option	The press of a single configured fluorescence button on the surgical microscope activates the fluorescence function	Configuration management enables the fluorescence visualization accessory. Once enabled, the press of a single button on the user interface activates the fluorescence function.
Visualization of Real- time images	Yes	Yes
Display	Video and images are presented on monitor. Picture-in-picture available.	Video feed from surgical camera is displayed on a primary surgeon monitor and optionally a second monitor. Picture-in-picture available.
Termination of the fluorescence option	Determined by surgeon or will turn off automatically after 5 minutes.	Determined by surgeon by turning on/off of the fluorescence option.
Light Source	2x 300W Xenon lamps	5 LEDs with combined power of 5500 mW
White Light Application	400 - 700 nm	400 – 700 nm
Fluorescence Excitation/ Detection wavelength range	700 - 780 nm / 820 - 900 nm	748 - 802 nm / 820 - 1000 nm
Distance of Imaging Head to Patient	200 – 500 mm	300 – 650 mm
Camera Adaptation	Integrated into the microscope head	Integrated into the microscope head
Zoom	Motorized 6:1	Motorized (optical) 7:1 Digital up to 12:1
Autofocus	Yes	Yes
Control System	Personal Computer	Personal Computer
Storage	HDD, DVD	SSD

	Predicate Device **Carl Zeiss** **INFRARED 800 with the FLOW 800 option**	**Subject Device** **Synaptive Medical Inc.** **Modus IR**
Biocompatibility	No direct contact with the patient.	No direct contact with the patient.

VII. Tests Summary

Sterilization and Shelf Life

The device is provided non-sterile. Shelf-Life is not applicable.

Biocompatibility

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

Verification and Validation Testing

Software

Software verification and validation testing was conducted in accordance with FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Device Software Functions" to demonstrate that the software performs as intended and meets user needs.

Performance Bench Testing

Non-clinical verification and validation tests were performed with regards to the intended use, technical claims, requirement specifications and risk management results. Functional and system level testing demonstrated that the device meets the defined specifications.

The following performance bench tests and evaluations were conducted for Modus IR as comparison tests to the predicate device in support of the substantial equivalence determination and to ensure that the clinically relevant parameters for the Indications for Use of Modus IR are fulfilled:

Table 2. Performance Bench Testing Summary

Test	Test Method Summary	Results
Signal-to-noise ratio (Sensitivity)	Imaging of an ICG-equivalent concentration sensitivity target was conducted with both Subject and Predicate devices. The sensitivity of Modus IR and the predicate was measured across a range of working distances and at the maximum zoom where the full target is visible. At each working distance and zoom, the limit of detection and the limit of quantification were calculated. The values were then compared between the two devices.	Pass – Modus IR was found to have lower limit of detection and limit of quantification than the predicate at comparable working distances.

Test	Test Method Summary	Results
Fluorescence excitation and emissions	Review of excitation and emission wavelengths used by Modus IR to excite and detect indocyanine green (ICG) were compared to those used by the predicate device.	Pass - Although the excitation and emissions wavelengths of Modus IR and the predicate are not identical, they are considered equivalent.
Non-deformed, non-rotated, non-mirrored, and centered video image	Review of data gathered during the in-vivo animal study where Modus IR and the predicate were directly compared. A white light screenshot taken from each system was compared to a freeze frame from an IR video clip recorded on the system after the screenshot was taken. The infrared image was qualitatively assessed.	Pass – IR images from Modus IR were found to be non-deformed, non rotated, non-mirrored and centered relative to the white light image.
Spatial resolution	Imaging of a resolution target made of ICG-equivalent material that fluoresces in the NIR spectrum was conducted with both Modus IR and predicate device. The horizonal and vertical spatial resolution of each system was measured across a range of working distances and zooms. The values were then compared between equivalent working distances and zooms of the two devices.	Pass – Modus IR was found to have a higher spatial resolution than the predicate at each working distance and zoom configuration, including at maximum zoom.
Photometric resolution	Quantization of the noise and number of levels available per pixel (as determined by the bit-depth) were compared between Modus IR and the predicate device.	Pass – Photometric resolution was found to be equivalent between Modus IR and the predicate.
Latency to external monitor	For both Modus IR and the predicate device, image latency to the same external monitor was measured and compared.	Pass – Average latency of Modus IR was found to be lower than the predicate.

In all performance bench tests and evaluations, Modus IR was found to perform as well or better than the predicate device. Based on these results, the images produced by Modus IR were equivalent to, or better than, those of the predicate device.

In vivo Animal Testing

An in vivo animal study was conducted in compliance with 21 CFR Part 58 (Good Laboratory Practice for Nonclinical Laboratory Studies) to confirm that Modus IR enables viewing of intraoperative blood flow and vessel architecture in a manner that is functionally equivalent to the predicate device INFRARED 800.

The study involved performing a cortical exposure in two healthy porcine models and capturing in vivo video clips of ICG flowing through vasculature using both the subject and predicate devices.

Four comparative video sets were obtained and assessed by 10 neurosurgeons for equivalence, resulting in 40 comparative evaluations. The neurosurgeons were blinded to which system they were evaluating, and the video sets were presented to them in a randomized order and in a clinically equivalent setup on an external monitor as recommended by the user manuals for both the subject and predicate devices.

Results: In all evaluations, intraoperative blood flow and vessel architecture visualization was found to be functionally equivalent between Modus IR and INFRARED 800 (100% confirmation). Additionally, all IR Fusion video clips from Modus IR were found to be suitable for the visualization of intraoperative blood flow against background anatomical structures (100% confirmation).

The in vivo animal testing confirmed that Modus IR meets its intended use and provides functionally equivalent visualization of intraoperative blood flow and vessel architecture when compared to the predicate device.

VIII. Conclusion

The intended use for Modus IR is similar to the intended use of the predicate device, INFRARED 800 with FLOW 800 option. The technological characteristics of the subject device are similar to those of the predicate device, and the differences have been validated and do not raise any new questions of safety and effectiveness. Results of the verification and validation testing, comparative performance bench testing and in vivo animal study demonstrated that Modus IR is as safe and effective and performs as well as the predicate device. Therefore, Modus IR is substantially equivalent to the predicate, INFRARED 800 with FLOW 800 option.