



April 17, 2026

Conavi Medical, Inc.  
% Sophia Farcas  
Regulatory Consultant  
Avania  
250 Carlaw Ave., Suite 108  
Toronto, Ontario M4M 3L1 CAN

Re: K252945  
Trade/Device Name: Novasight Hybrid System  
Regulation Number: 21 CFR 870.1200  
Regulation Name: Diagnostic Intravascular Catheter  
Regulatory Class: Class II  
Product Code: OBJ, NQQ, IYO  
Dated: March 18, 2026  
Received: March 18, 2026

Dear Sophia Farcas:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for: **MARCO CANNELLA -S**

Aneesh Deoras  
Assistant Director  
Division of Cardiac Electrophysiology,  
Diagnostics, and Monitoring Devices  
Office of Cardiovascular Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252945

?

Please provide the device trade name(s).

?

Novasight Hybrid System

Please provide your Indications for Use below.

?

The Novasight Hybrid System is intended for intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

## 510(k) Summary

**510(k) Number: K252945**

### Applicant Information:

Date Prepared: April 9, 2026  
Name: Conavi Medical Inc.  
Address: 293 Lesmill Road  
North York, ON, Canada M3B 2V1

Contact Person: Sophia Farcas  
sophia.farcas@avaniaclinical.com  
Mobile Number: +1 (647) 970-7959

### Device Information:

Trade/Proprietary Name: Novasight Hybrid System  
Common Name: Novasight Hybrid System  
Classification Name: Diagnostic Intravascular Catheters, 21 CFR 870.1200  
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560

Product Code: OBJ, NQQ, IYO  
Class: Class II  
Panel: Division of Cardiovascular Devices

### Predicate Device:

- Conavi Medical Inc., Novasight Hybrid System (v1.0), K172258

### Device Description:

The Novasight Hybrid System provides co-registered intravascular ultrasound (IVUS) and optical coherence tomography (OCT) images of the coronary arteries in patients who are candidates for transluminal interventional procedures.

The System is comprised of the following components:

- Console
- Patient Interface Module (PIM)
- Bedside Controller (BSC)
- Catheter
- Bedside Panel (BSP)

The Console is a mobile-based cart that receives raw imaging signals from the catheter via the PIM, processes the data, and displays the resulting IVUS and OCT images. The Console is

used to input catheter commands for image acquisition, process, construct, and display the imaging data, and user interface with the imaging data (enhance, manipulate, annotate, measure, and store clinical images).

The Console additionally contains four AI algorithms used for feature detection in captured IVUS and OCT images. The Sheath Detection Algorithm (OCT) estimates the radius of the sheath in OCT frames, the Lumen Detection Algorithm (OCT) extracts a set of evenly spaced points representing the lumen border in OCT frames, the EEL and Lumen Detection Algorithm (IVUS) extracts two sets of evenly spaced points, with one representing the EEL border and one representing the lumen border, in IVUS frames, and the Stent Strut Detection Algorithm (OCT) extracts a set of points locating the stent struts in OCT frames. All algorithms were trained using a combination of clinical, animal, human cadaver, and bench data. The Lumen Detection (OCT), EEL and Lumen Detection (IVUS), and Stent Strut Detection (OCT) models were validated using separate human cadaver and animal data. The Sheath Detection Algorithm (OCT) was validated by demonstrating measurement accuracy against known measurements was within the device's OCT measurement tolerance using separate bench and animal data.

The PIM is the electromechanical interface between the Catheter and the Console and is situated outside the sterile field.

The BSC contains a joystick and programmable buttons to input commands for image acquisition and image review functions (scrolling, measurement, annotation) that are also available on Console, allowing physicians to control the system without leaving the sterile field.

The Catheter is a sterile, single use device that integrates both an ultrasound transducer and an optical imaging assembly, to simultaneously transmit acoustic and optical energy into the surrounding tissue. The resulting signals are detected by the Catheter and sent to the Console software via the PIM to produce 2 synchronized and co-registered images of the artery: one ultrasonic and one optical. The catheter is compatible with a  $\geq 5\text{Fr}$  guide catheter and is advanced over a 0.014" guidewire via femoral or radial access.

The BSP facilitates network connectivity and serves as a centralized connection hub between the Novasight Hybrid System components and other cath lab equipment.

### **Indications for Use:**

The Novasight Hybrid System is intended for intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

**Functional and Technological Comparison:**

Table 1 below provides a functional and technological comparison between the Novasight Hybrid System (v3.0) and FDA-cleared Novasight Hybrid System (v1.0) (K172258). Both devices have the same intended use, indications for use, mechanism of action, and principles of operation. Technological differences between devices include system configuration changes with the addition of two (2) new components, catheter design changes, new software functions, and improved system performance and image quality. These technological differences do not raise new or different questions of safety and effectiveness.

	<b><u>Subject Device</u></b> <b>Conavi Medical Inc.</b> <b>Novasight Hybrid System (v3.0)</b>	<b><u>Predicate Device</u></b> <b>Conavi Medical Inc.</b> <b>Novasight Hybrid System (v1.0)</b> <b>(K172258)</b>	<b>Comparison</b>
Classification	II	II	Same
Product Code	OBJ, NQQ, IYO	OBJ, NQQ, IYO	Same
Intended Use	Intravascular imaging	Intravascular imaging	Same
Indications for Use	The Novasight Hybrid System is intended for intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.	The Novasight Hybrid System is intended for intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.	Same
Mechanism of Action	Emits ultrasound and infrared light from a rotating and translating imaging core; reflected IVUS and OCT signals are captured, processed, and co-registered to produce real-time cross-sectional images.	Emits ultrasound and infrared light from a rotating and translating imaging core; reflected IVUS and OCT signals are captured, processed, and co-registered to produce real-time cross-sectional images.	Same
System Components	Catheter, Console, Patient Interface Module (PIM), Bedside Controller (BSC), Bedside Panel (BSP)	Catheter, Console, PIM	Similar
Imaging Modes	B-Mode IVUS, B-Mode OCT	B-Mode IVUS, B-Mode OCT	Same
Ultrasound Frequency	50 MHz, broadband	40 MHz	Similar
Optical Wavelength	1310 nm	1310 nm	Same
Acoustic Output	Does not exceed Track 1 limits.	Does not exceed Track 1 limits.	Same
Crossing profile in imaging window (Nominal)	2.6 Fr	2.8 Fr	Similar

	<b>Subject Device</b> <b>Conavi Medical Inc.</b> <b>Novasight Hybrid System (v3.0)</b>	<b>Predicate Device</b> <b>Conavi Medical Inc.</b> <b>Novasight Hybrid System (v1.0)</b> <b>(K172258)</b>	<b>Comparison</b>
Catheter Working Length	149 cm	149 cm	Same
Compatible Guidewire	0.014”	0.014”	Same
Minimum Guide Catheter Compatibility	≥5Fr	≥6Fr	Similar
Rotational Speed	30–140 RPS	30–100 RPS	Similar
Pullback Length	10 cm	10 cm	Same
Pullback Speed	1-40 mm/s	0.5-25 mm/s	Similar
Sterilization Method	E-beam	E-beam	Same
Single Use Components	Catheter only	Catheter only	Same
Feature Detection & Measurements	Detected automatically and/or manually traced by user.	Manually traced by user.	Similar

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**Performance Testing:**

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

- **Sterilization, Packaging and Shelf-Life**

Sterilization and sterile barrier system packaging of single use components were validated. Shelf life testing verified that device sterility and performance was maintained after accelerated aging.

- **Shipping and Useful Life**

Device components were subjected to simulated transport testing in accordance with ASTM D4169. Useful life testing verified device performance was maintained after simulated reprocessing of reusable components.

- **Biocompatibility**

Patient contacting device components underwent biocompatibility testing in accordance with FDA Guidance and ISO 10993-1.

- **Software Verification & Validation**

Software verification and validation was conducted, which included the validation of the newly introduced algorithms. Documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

- **Electrical Safety and Electromagnetic Compatibility**

Testing was performed according to IEC 60601-1, IEC 60601-2-37, IEC 60601-2-18, and IEC 60601-1-2.

- **Bench Testing**

Bench testing was conducted at both the component and system level against known standards or product specifications. Performance testing was performed under conditions simulating intended use (simulated use testing) where applicable.

- **Human Factors**

Summative human factors validation testing was conducted according to FDA Guidance: "Applying Human Factors and Usability Engineering to Medical Devices".

Performance test results were analyzed to demonstrate substantially equivalent performance. Results demonstrate that the Novasight Hybrid System (v3.0) is substantially equivalent to the predicate Novasight Hybrid System (v1.0) (K172258).

**Predetermined Change Control Plan (PCCP):**

The Novasight Hybrid System (v3.0) includes a Predetermined Change Control Plan (PCCP) for certain AI-enabled software functions, consistent with FDA's guidance "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions".

Specifically, the planned modifications allow for retraining of the OCT Sheath Detection

Algorithm, the OCT Lumen Detection Algorithm, the IVUS EEL and Lumen Detection Algorithm, and/or the OCT Stent Struct Detection Algorithm, subject to the availability of sufficient retraining and validation data. Any retraining modifications shall be subject to design validation following the same methodology and acceptance criteria as used to originally validate the AI algorithms for 510(k) clearance.

Following the release of any PCCP modifications, version release notes will be communicated to all users of the device. These release notes will include a description of all modifications made between the old and new version of the software, transparency on any differences in performance based on the modifications, and, if applicable, any known issues that were addressed in the update. Additionally, all device labelling will be updated to reflect the latest version of the modified algorithm(s).

**Conclusion:**

The Novasight Hybrid System (v3.0) subject device, is substantially equivalent to the Novasight Hybrid System (v1.0) (K172258) predicate device. Both devices have the same intended use, indications for use, mechanism of action, and principles of operation. The technological differences between the subject and predicate device do not raise different questions of safety or effectiveness. Performance data demonstrates that the Novasight Hybrid System (v3.0) performs as intended and in a manner that is substantially equivalent to the predicate device. Accordingly, Conavi Medical Inc. concludes that the Novasight Hybrid System (v3.0) is safe and effective for its intended use, is as safe and effective as the predicate device, and is therefore substantially equivalent to the Novasight Hybrid System (v1.0) (K172258).