June 4, 2026

Covidien, LLC
Atbin Malayeri
Principal Regulatory Affairs Specialist
15 Hampshire St.
Mansfield, Massachusetts 02048

Re: K253984
Trade/Device Name: Instrument Exit Point on Touch Surgery™ Aide
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: SFE, QZB
Dated: December 12, 2025
Received: December 12, 2025

Dear Atbin Malayeri:

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 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.06.04 14:33:51 -04'00'

Tanisha Hithe, MS, MHS
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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.	K253984

Please provide the device trade name(s).

Instrument Exit Point on Touch Surgery™ Aide

Please provide your Indications for Use below.

Indications for Use Statement: The Instrument exit point application is indicated for use as an adjunct during surgical procedures performed using the Hugo™ Robotic-Assisted Surgery (RAS) system, in accordance with the FDA-cleared indications for use of the Hugo RAS system. The Instrument exit point application does not expand, modify, or replace the indications for use of the Hugo RAS system; refer to the Hugo™ RAS labeling for the applicable indications for use.

Intended Use Statement: The Instrument Exit Point application is an AI-enabled device software function that is intended to analyze the visual field and data available, in real-time, during the procedure, providing information to assist and support the surgeon

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

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

Medtronic

1. Submitter's Information

Manufacturer:	Covidien LLC
Address:	15 Hampshire Street Mansfield Massachusetts 02048 USA
Contact:	Mr. Atbin Malayeri
Company Contact Person:	atbin.malayeri@medtronic.com

2. Subject Device

Device Trade Name:	Instrument Exit Point on Touch Surgery™ Aide
Device Common Name:	Software Component For Real Time Video Augmentation
Classification Regulation Number:	21 CFR 876.1500
Device Regulation Name:	Endoscope and Accessories
Device Classification:	Class II
Device Product Codes:	SFE, QZB
510(k) Number	K253984
Date Prepared	June 2nd, 2026

3. Predicate and Reference Devices

Predicate Device	Marketing Authorization	Product Code
HyperSnap Surgical System (HSS)	K250268	SFE, FET, MUD

Reference Devices	Marketing Authorization	Product Code
Moon Surgical Maestro Robotic System	K242323	QZB
Hugo™ RAS System	K250725	SCV
Intuitive Surgical Endoscopic Instrument Control System	K021036	NAY

4. Device Description

4.1. General Description

The Instrument Exit Point (IEP) hosted on the Touch Surgery™ Aide platform is an adjunct, non-therapeutic, non-diagnostic, real-time AI-enabled software function that provides a visual overlay to assist intraoperative awareness of instrument exit. It achieves this by tracking specified Hugo™ RAS energy instruments and provides visual indicators when and where an instrument leaves the endoscope's field of view. The Instrument Exit Point application is intended for use during surgical procedures performed using the Hugo™ Robotic-Assisted Surgery (RAS) System, in accordance with the FDA-cleared indications for use of the Hugo™ RAS System, including type of endoscopes (KARL STORZ IMAGE1 S™ RUBINA™ endoscope TC201), surgical specialties and instruments. IEP processes endoscopic video at an approximate rate of 10 frames per second (fps), with a tolerance of ±1 frame per second.

The Instrument Exit Point is supported when using the Hugo™ RAS system with the following Hugo™ RAS instruments:

- Bipolar Maryland forceps (MRASI0005)
- Bipolar fenestrated grasper (MRASI0004)
- Monopolar curved shears (MRASI0001)

The hosting platform, an internally developed Touch Surgery™ Aide Computer with an off-the-shelf tablet Controller and Monitor, is used to capture, process, display, and manage surgical video.

4.2. Statement of Intended Use

Intended Use statement:	The Instrument Exit Point application is an AI-enabled device software function that is intended to analyze the visual field and data available, in real-time, during the procedure, providing information to assist and support the surgeon.
Indication for Use statement:	The Instrument Exit Point application is indicated for use as an adjunct during surgical procedures performed using the Hugo™ Robotic-Assisted Surgery (RAS) system, in accordance with the indications for use of the Hugo™ RAS system. The Instrument exit point application does not expand, modify, or replace the indications for use of the Hugo™ RAS system; refer to the Hugo™ RAS labeling for the applicable indications for use.

5. Comparison

The table below compares the Instrument Exit Point (IEP) on Touch Surgery™ Aide to the predicate device.

Aspect	Subject Device	Predicate
Device Name	Instrument Exit Point	HyperSnap Surgical System
510(k) Number	K253984	K250268
Product Code	SFE, QZB	SFE, FET, MUD
Intended Use	The Instrument Exit Point application is an AI-enabled device software function that is intended to analyze the visual field and data available, in real-time, during the procedure, providing information to assist and support the surgeon.	The HyperSnap Surgical system is intended to be used intraoperatively to relay a standard RGB video feed used for visualization alongside corresponding AI-enabled visualization insights in the form of tissue oxygenation information presented as a corresponding two-dimensional real-time video feed.
Indications for Use	The Instrument Exit Point application is an AI-enabled device software function that is indicated for use during robotic-assisted surgery with Hugo™ RAS to detect when the supported instruments leave the field-of-view.	The system is intended for use as an adjunctive monitor of the hemoglobin oxygen saturation of blood (StO2) in the superficial tissue in the surgical field of view.
Brief Description	Instrument Exit Point provides real-time notification to the surgeon when and where a supported Hugo™ RAS energy instrument(s) has left the surgeon's field-of-view, with information displayed as an overlay on the Touch Surgery™ Aide monitor.	The HSS provides for visualization of real-time tissue oxygenation saturation (StO2) information alongside conventional red-green-blue (RGB) visualization.
Mechanism of Action	Software analysis of white light endoscopic visualization	Software analysis of conventional RGB endoscopic visualization
Development Method	Machine Learning methodology used to develop software algorithm responsible for detecting the supported instrument's position. Once developed, this software algorithm is fixed and static and added to Touch Surgery™ Aide platform software.	Machine Learning methodology used to develop software algorithm responsible for extraction of advanced optical properties of observed tissues alongside conventional red-green-blue (RGB) visualization. Once developed, this software algorithm is fixed and static and added to computational workstation.
AI/ML Class of the Model	A deep learning-based instrument detection and localization algorithm	The deep learning-based super-resolution and reconstruction algorithm
Video Image Handling	The video image is transferred from the endoscope through the Aide Medical Device Data System (MDDS), to the AI Application.	The video image is transferred from the laparoscope through the computer to the ML algorithm.
Image Processing Instrument Identification Algorithm	The IEP AI application identifies the subject instruments (object predictions) with bounding boxes, instrument class, and key points, tracks the instruments across frames, and identifies when an instrument leaves the field of view (FOV).	N/A

Aspect	Subject Device	Predicate
Intended User	RAS surgeon	Lap surgeon
Procedural Population	RAS per the Hugo™ Robotic System	MIS/Open surgery
System components	1. AI-enabled algorithm and software function on the Touch Surgery™ Aide system 2. Touch Surgery™ Aide MDDS system comprises of four main hardware elements: - Touch Surgery™ Aide Computer - Touch Surgery™ Aide Controller - Touch Surgery™ Aide Cart - Touch Surgery™ Aide Monitor	1. ML-enabled algorithms and software function on the computational work system 2. hyperspectral camera 3. Computational workstation 4. Camera Control Unit (CCU) 5. Camera Electrical Isolator 6. Camera Electrical Isolator Power Supply.
ML Software Testing	Software testing included Performance Evaluation of the AI algorithm across benchmarked datasets. Integration/Interoperability Testing between the AI and MDDS systems in accordance with the Multiple Function Device Impact Analyses to provide mutual design verification coverage.	Testing evaluated image reconstruction across benchmark datasets using objective metrics (PSNR, SSIM, and reconstruction fidelity). The reconstruction fidelity metric was verified against an independent, previously unseen invivo dataset representative of clinical use.
Performance Testing	• Clinical Performance assessment including ex-vivo tissue model studies • Usability & Human factors testing	• GLP Animal Studies • Human Factors Testing

6. Consensus Standards

The Instrument Exit Point application software function conforms to IEC 62304, ISO 14971, IEC 62366-1, IEC 15223-1, and ISO 20417.

Standard Reference	Consensus Recognition Number	Conformity Assessment
IEC 62304:2006/A1:2016 — Medical device software — Software life cycle processes	13-79	Declaration of conformity
IEC 62366-1:2015+AMD1:2020 — Medical devices — Part 1: Application of usability engineering to medical devices	5-129	Declaration of conformity
ISO 14971:2019 — Medical devices — Application of risk management to medical devices	5-125	Declaration of conformity

Standard Reference	Consensus Recognition Number	Conformity Assessment
ISO 15223-1:2021 — Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	5-134	Declaration of conformity
ISO 20417:2021 — Medical devices — Information to be supplied by the manufacturer	5-135	Declaration of conformity

7. Software Verification and Validation Testing

Software verification and validation testing were performed for the Instrument Exit Point (IEP) software application in accordance with FDA's "Content of Premarket Submissions for Device Software Functions", June 2023 Guidance and relevant international standards. Enhanced Documentation was provided. Testing encompassed all subject device software features, including detection and notification of instrument exit events, user interface behavior, and integration with the Touch Surgery™ Aide platform. Performance Testing activities combine software verification, standalone quantitative bench verification of the AI-enabled device software function (IEP) using representative clinical videos, and simulation-based clinical use, usability and human factors evaluations in mock operating room settings.

8. Artificial Intelligence

The device incorporates a locked machine-learning algorithm that analyzes live, white-light endoscopic RGB video during robotically assisted procedures to determine when supported instruments leave the endoscope's field of view. Its functionality is adjunct and information-only. As instrument exits the visible field, the software displays a real-time on-screen indicator showing the last-seen location. The feature does not diagnose, treat, or control equipment and does not display or infer instrument position outside the field of view; users remain fully responsible for clinical decisions and must move instruments only under direct endoscopic visualization. No Predetermined Change Control Plan is included with this submission.

The AI/ML approach uses a real-time detection and tracking method to identify supported instruments in the video stream and to determine exit events frame-to-frame. The intended input data are live, white-light endoscopic video from procedures performed with the compatible Hugo™ RAS in an operating room environment by trained healthcare professionals; the intended output is a supplemental visual overlay presented on the Touch Surgery™ Aide Monitor (display).

Algorithm development used clinically representative surgical video for training and development, with performance established on independently separated validation and testing datasets. Testing was conducted on data sets that were not used for training to confirm generalizability to the intended use. Primary performance metrics comprised temporal accuracy for detecting instrument exit and re-entry events, sensitivity and specificity for event detection, and spatial accuracy of the last-seen indicator; testing met predefined acceptance criteria appropriate to the device's adjunct, information-only purpose, with results demonstrating reliable and timely indication of instrument exit events.

Key limitations and considerations for safe and effective use are reflected in the user interface and labeling. The indicator is time-limited to mitigate over-reliance and is clearly labeled to communicate that it marks the exit point rather than a real-time instrument location; the feature is optional and intended only for supported instrument types and white light endoscopy in adult patients as specified in labeling; adequate video quality and lighting are required for proper operation. Warnings and cautions emphasize reliance on direct visualization and professional judgment at all times. Usability and simulated-use evaluations confirmed interpretability and appropriate cognitive load in the intended environment.

9. Conclusion

In summary, Instrument Exit Point application (IEP application) is an adjunct, real-time visualization feature that indicates to surgeons when Hugo™ RAS instruments leave the endoscopic field of view, with the Instrument Exit location displayed on the Touch Surgery™ Aide Monitor (please note, the Touch Surgery™ Aide Monitor is adjunct to Hugo™ RAS displays). The IEP application and the predicate devices are intended for the same use as intraoperative, real-time visualization tools. Both utilize AI-enabled software to analyze endoscopic video and provide supplementary information to the surgeon. Any differences in the indications or technological characteristics do not introduce new questions regarding safety or effectiveness. Therefore, based upon the Intended Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Instrument Exit Point Application hosted on the Touch Surgery™ Aide platform has been shown to be substantially equivalent to the cited predicate devices.