



Ever Fortune.AI, Co., Ltd.  
Ti-Hao Wang  
Chief Technology Officer  
8F., No.360, Sec. 1, Jingmao Rd., Beitun Dist.  
Taichung City, 406040  
Taiwan

April 22, 2026

Re: K253163

Trade/Device Name: Efai Ersuite CT Appendicitis Assesment System (APPEN-CT-100)  
Regulation Number: 21 CFR 892.2080  
Regulation Name: Radiological Computer Aided Triage And Notification Software  
Regulatory Class: Class II  
Product Code: QAS  
Dated: March 19, 2026  
Received: March 19, 2026

Dear Ti-Hao Wang:

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

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

Jessica Lamb, Ph.D

Assistant Director

DHT8B: Division of Radiological Imaging  
Devices and Electronic Products

OHT8: Office of Radiological Health

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.

K253163

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Please provide the device trade name(s).

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EFAI ERSUITE CT APPENDICITIS ASSESSMENT SYSTEM (APPEN-CT-100)

Please provide your Indications for Use below.

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EFAI ERSUITE CT APPENDICITIS ASSESSMENT SYSTEM (EFAI APPENDICITIS) is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced abdominal CT images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of appendicitis.

EFAI APPENDICITIS uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of EFAI APPENDICITIS are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

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)

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## 510(k) Summary

### 1. General Information

<b>510(k) Sponsor</b>	Ever Fortune.AI Co., Ltd.
<b>Address</b>	8F., No.360, Sec. 1, Jingmao Rd., Beitun Dist., Taichung City 406040, Taiwan
<b>Applicant</b>	Joseph Chang
<b>Contact Information</b>	886-04-23213838 #216 joseph.chang@everfortune.ai
<b>Correspondence Person</b>	Ti-Hao Wang
<b>Contact Information</b>	886-04-23213838 #168 <a href="mailto:thothwang@gmail.com">thothwang@gmail.com</a> tihao.wang@everfortune.ai
<b>Date Prepared</b>	April 22, 2026

### 2. Proposed Device

<b>Proprietary Name</b>	EFAI ERSUITE CT APPENDICITIS ASSESSMENT SYSTEM (APPEN-CT-100 )
<b>Common Name</b>	EFAI APPENDICITIS
<b>Classification Name</b>	Radiological computer-assisted triage and notification software
<b>Regulation Number</b>	21 CFR 892.2080
<b>Product Code</b>	QAS
<b>Regulatory Class</b>	II

### 3. Predicate Device

<b>Proprietary Name</b>	BriefCase
<b>Premarket Notification</b>	K193298
<b>Classification Name</b>	Radiological computer-assisted triage and notification software
<b>Regulation Number</b>	21 CFR 892.2080
<b>Product Code</b>	QAS
<b>Regulatory Class</b>	II



#### **4. Device Description**

EFAI ERSUITE CT APPENDICITIS ASSESSMENT SYSTEM (EFAI APPENDICITIS) is a radiological computer-assisted triage and notification software system. The software uses deep learning techniques to automatically analyze contrast-enhanced abdominal computed tomography (CT) and alerts the PACS/RIS workstation once images with features suggestive of appendicitis are identified.

Through the use of EFAI APPENDICITIS, a trained clinician is able to review studies with features suggestive of appendicitis earlier than in standard of care workflow.

The device is intended to provide a passive notification through the PACS/workstation to the trained clinicians indicating the existence of a case that may potentially benefit from the prioritization. It does not mark, highlight, or direct users' attention to a specific location on the original contrast-enhanced abdominal CT. The device aims to aid in prioritization and triage of radiological medical images only.

#### **5. Intended Use / Indications for Use**

EFAI ERSUITE CT APPENDICITIS ASSESSMENT SYSTEM (EFAI APPENDICITIS) is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced abdominal CT images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of appendicitis.

EFAI APPENDICITIS uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of EFAI APPENDICITIS are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.



## 6. Comparison of Technological Characteristics with Predicate Device

The subject device EFAI APPENDICITIS and the predicate BriefCase for IFG triage (K193298) are AI-based radiological triage and notification software intended for use with CT scanners, PACS, and radiology workstations. Both accept abdominal CT images as input, apply AI algorithms to identify suspected positive findings, and generate case-level notifications to clinicians.

The subject device processes contrast-enhanced abdominal CT images and is designed to detect appendicitis. The predicate device processes abdominal CT images without restriction on contrast use and is designed to detect Intra-abdominal Free Gas (IFG).

In terms of output, the predicate provides notifications containing compressed preview images, whereas the subject device provides text-based notifications without images. Both devices operate in parallel to the standard of care workflow, do not alter or annotate the original medical images, and do not remove or reprioritize cases from the reading queue.

A table comparing the key features of the subject device and predicate devices is provided below.

<b>Feature/ Function</b>	<b>Proposed Device: EFAI APPENDICITIS</b>	<b>Predicate Device: <i>BriefCase</i> (K193298)</b>
<b>Intended Use/Indication for Use</b>	<p>EFAI ERSUITE CT APPENDICITIS ASSESSMENT SYSTEM (EFAI APPENDICITIS) is a radiological computer aided triage and notification software indicated for use in the analysis of contrast-enhanced abdominal CT images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of appendicitis.</p> <p>EFAI APPENDICITIS uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. The device does not alter the original medical image and is not intended to be used as a diagnostic device.</p>	<p>BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of abdominal CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Intra-abdominal free gas (IFG) pathologies. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The</p>

	The results of EFAI APPENDICITIS are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	results of BriefCase are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.
<b>User Population</b>	Trained clinician	Trained radiologist
<b>Anatomical Region of Interest</b>	Abdomen	Abdomen
<b>Data Acquisition Protocol</b>	Contrast-enhanced abdominal CT	Abdominal CT scan
<b>Images Format</b>	DICOM	DICOM
<b>Interference with Standard Workflow</b>	No. No cases are removed from Worklist or deprioritized.	No. No cases are removed from desktop app or deprioritized.
<b>Algorithm</b>	Artificial intelligence algorithm with database of images.	Artificial intelligence algorithm with database of images.
<b>View DICOM data</b>	No	DICOM Information about the patient, study and current image
<b>Segmentation of region of interest</b>	No; device does not mark, annotate, or direct users' attention to a specific location in the original image	No; device does not mark, annotate, or direct users' attention to a specific location in the original image
<b>Notification/Prioritization</b>	Yes	Yes
<b>Preview images</b>	No	Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.
<b>Alteration of original image</b>	No	No



<b>Removal of cases from worklist queue</b>	No	No
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## 7. Performance Data

Performance of the EFAI APPENDICITIS has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with IEC 62304:2006/A1:2015 - Medical device software – Software life cycle processes, in addition to the FDA Guidance documents, “Content of Premarket Submissions for Device Software Functions” and “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.”

Ever Fortune.AI conducted a retrospective, blinded, multisite validation study of the proposed device, EFAI APPENDICITIS, using pre-specified primary and secondary endpoints with corresponding performance goals.

The study evaluated 300 consecutively collected contrast-enhanced abdominal CT cases from multiple U.S. clinical sites, with one case per patient. None of these cases were used in model development or internal testing. The appendicitis status of each case was independently assessed by three U.S. board-certified radiologists, with the reference standard (ground truth) determined by majority agreement, yielding 139 positive and 161 negative cases. The primary endpoints were sensitivity and specificity, each with a performance goal of 0.8.

EFAI APPENDICITIS demonstrated sensitivity of 0.928 (95% CI: 0.873–0.960) and specificity of 0.932 (95% CI: 0.882–0.961), exceeding the performance goals and showing substantial equivalence to the predicate device, with sensitivity of 0.910 (95% CI: 0.815–0.967) and specificity of 0.889 (95% CI: 0.817–0.940). The secondary endpoint, mean system processing time per case, was 3.37 minutes (95% CI: 3.34–3.40), which was significantly less than the pre-specified goal.

Moreover, subgroup analyses across sex, age, race/ethnicity, CT manufacturer, and CT slice thickness showed consistent performance, underscoring reliability across diverse populations and imaging conditions. Additional evaluations in cases with different levels of appendiceal thickening and other potential confounding factors (e.g., appendiceal findings, inflammatory or infectious conditions, suboptimal image quality issues, diverticulitis, urinary findings, gynecological findings, vascular or ischemic conditions, fluid collections, neoplastic or metastatic lesions, and postoperative findings) were also conducted accordingly.

In conclusion, the results demonstrate that EFAI APPENDICITIS is substantially equivalent to the predicate device.



EFAI APPENDICITIS has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with ISO 14971:2019 Medical devices — Application of risk management to medical devices. The EFAI APPENDICITIS performance has been validated using retrospective data from case data and through the use of Reader comparison analysis.

## **8. Substantial Equivalence**

The indications for use statement for the subject device, EFAI APPENDICITIS, is substantially similar to the cleared indications for use statement for BriefCase (K193298). Both the subject and predicate devices are radiological computer-aided triage and notification software intended to assist hospital networks in workflow triage by flagging and communicating suspected positive findings based on abdominal CT images. Although the clinical findings differ and there is variation in contrast use, both devices analyze the same abdominal CT region, and these differences do not impact the underlying technology or raise new performance concerns.

Both devices target the same user population, focus on the abdomen as the anatomical region of interest, utilize abdominal CT as the data acquisition protocol, support notifications as a parallel workflow tool, and use DICOM format for images. They also employ similar artificial intelligence algorithms for analyzing images. Both operate in parallel to the standard of care workflow, meaning they do not change the original images, do not provide any markings on the images, and do not remove or reprioritize cases from the standard queue.

The EFAI APPENDICITIS has minor technical differences compared to the predicate device. The predicate device provides preview images within their notification while the proposed device provides notification as a text based JSON file. This difference does not change the fundamental technology of the device, which is the use of AI algorithms to process images and generate case-level notifications for triage purposes. These differences do not raise new questions of safety or effectiveness compared to the predicate.

## **9. Conclusion**

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, and performance testing, the EFAI APPENDICITIS is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.