

FW23744, KH23403, KH23404 or P/N LV11570”, this AD requires replacing that text with “P/N FK23411, FW23643, FW23741, FW23744, FK25441, FK25968, FW11901, FW15393, KH23403, KH23404, or LV11570, installed”.

(4) This AD does not adopt the “Remarks” paragraph of EASA AD 2025–0144.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2025–0144 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the AIR–520 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (k) of this AD and email to: AMOC@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Additional Information

For more information about this AD, contact Alexis Whitaker, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (516) 228–7309; email: alexis.j.whitaker@faa.gov.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2025–0144, dated July 9, 2025.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: ADs@easa.europa.eu; website: easa.europa.eu. You may find this material on the EASA website at ad.easa.europa.eu.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov.

Issued on August 28, 2026.

Brian Knaup,

Acting Deputy Director, Integrated Certificate Management Division, Aircraft Certification Service.

[FR Doc. 2026–18559 Filed 9–10–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2026–N–9907]

Medical Devices; Cardiovascular Devices; Classification of the Cardiovascular Machine Learning-Based Notification Software

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the cardiovascular machine learning-based notification software into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for classification of the cardiovascular machine learning-based notification software. We are taking this action because we have determined that classifying the device into class II will provide a reasonable assurance of the safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective September 11, 2026. The classification was applicable on August 3, 2023.

FOR FURTHER INFORMATION CONTACT:

Hetal Odobasic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2108, Silver Spring, MD 20993–0002, 240–402–6540, Hetal.Odobasic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA (the Agency or we) has classified the cardiovascular machine learning-based notification software into class II (special controls), which we have determined will provide a reasonable assurance of the safety and effectiveness of the device. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens

by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified into, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo classification process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a premarket notification (510(k)) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a

classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining "substantial equivalence"). Instead, sponsors can use the less

burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On January 10, 2023, FDA received Viz.ai, Inc.'s request for De Novo classification of the Viz HCM device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see section 513(a)(1)(B) of the FD&C Act). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the

general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 3, 2023, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 870.2380.¹ We have named the generic type of device "cardiovascular machine learning-based notification software," and it is identified as software that employs machine learning techniques to suggest the likelihood of a cardiovascular disease or condition for further referral or diagnostic follow-up. The software identifies a single condition based on one or more non-invasive physiological inputs as part of routine medical care. It is intended as the basis for further testing and is not intended to provide diagnostic quality output. It is not intended to identify or detect arrhythmias.

FDA has identified the risks to health associated with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR CARDIOVASCULAR MACHINE LEARNING-BASED NOTIFICATION SOFTWARE

Identified risks to health	Mitigation measures
False positive or false negative leading to incorrect treatment or diagnosis.	Clinical performance testing; Non-clinical performance testing; and Labeling.
Incorrect treatment or diagnosis due to model bias or failure to adequately generalize to the intended use population.	Clinical performance testing; and Labeling.
Device used in unsupported patient population or with unsupported input/hardware.	Labeling; Human factors assessment; and Software verification, validation, and hazard analysis.
Overreliance on device output for follow-up	Human factors assessment; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness of the device. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this final order.

Under the FD&C Act, submission of a premarket notification under section 510(k) is required to reasonably assure the safety and effectiveness of class II devices unless FDA determines that the device type should be exempt under section 510(m) of the FD&C Act. At this time FDA has not made this determination for cardiovascular

machine learning-based notification software. This device is therefore subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not normally have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of

information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 regarding quality management system regulation have been approved under OMB control number 0910–0073;

¹ FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final order," rather than "Final order." Beginning in December 2019, this editorial change was made to

indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44

U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 870.2380 to subpart C to read as follows:

§ 870.2380 Cardiovascular machine learning-based notification software.

(a) *Identification.* Cardiovascular machine learning-based notification software employs machine learning techniques to suggest the likelihood of a cardiovascular disease or condition for further referral or diagnostic follow-up. The software identifies a single condition based on one or more non-invasive physiological inputs as part of routine medical care. It is intended as the basis for further testing and is not intended to provide diagnostic quality output. It is not intended to identify or detect arrhythmias.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following must be met:

(i) Clinical validation must use a test dataset of real-world data acquired from a representative patient population. Data must be representative of the range of data sources and data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment. The test dataset must be independent from data used in training/development and contain sufficient numbers of cases from important cohorts (e.g., demographic populations, subsets defined by clinically relevant confounders, comorbidities, and subsets defined by hardware and acquisition characteristics) such that the performance estimates and confidence intervals of the device for these individual subsets can be characterized for the intended use population and acquisition systems (e.g., acquisition hardware or preprocessing software).

Study protocols must include a description of the adjudication process(es) for determining ground truth of training and test datasets;

(ii) Data must be provided within the clinical validation study or using equivalent datasets to demonstrate the consistency of the output over the full range of inputs;

(iii) Performance goals used to determine success of clinical validation must be justified in the context of risks associated with follow-up testing;

(iv) Objective performance measures (e.g., sensitivity, specificity, positive predictive value or negative predictive value) must be reported with relevant descriptive or developmental performance measures. Summary level demographic information and sub-group analyses must be provided for each study site, relevant demographic sub-groups, and acquisition systems; and

(v) The test dataset must include a minimum of three geographically diverse sites, separate from sites used in training of the model.

(2) Software verification, validation, and hazard analysis must be performed. Software documentation must include:

(i) A description of the model/algorithm, algorithm inputs/outputs, and supported patient population;

(ii) Integration testing in the intended software system or software environment; and

(iii) A description of the expected impact of all applicable sensor acquisition hardware characteristics on performance and any associated hardware specifications, including:

(A) A description of input signal/data quality control measures; and

(B) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy.

(3) Human factors assessment of the intended users in the intended use environment must evaluate the risk of misinterpretation of device output.

(4) Labeling must include:

(i) A summary of the performance testing methods, tested hardware, tested/supported patient population, results of the performance testing for tested performance measures/metrics, summary-level descriptions of patient demographics and associated subgroup analyses for training and test datasets, and the expected minimum performance of the device;

(ii) Device limitations or subpopulations for which the device may not perform as expected;

(iii) Warning that the user should not rely on the lack of a suspected finding to rule out follow-up;

(iv) A statement that the device output should not replace a full clinical evaluation of the patient and that the output may not be sufficient as the sole basis for further testing;

(v) Warnings identifying sensor acquisition factors that may impact measurement results;

(vi) Guidance for interpretation of the measurements and typical follow-up testing; and

(vii) The type(s) of hardware sensor data used, including specification of compatible sensors for data acquisition.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18612 Filed 9–10–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 126

[Public Notice: 13103]

RIN 1400–AG34

Amendment to the International Traffic in Arms Regulations: Prohibited Exports, Imports, and Sales to or From Certain Countries—Cyprus

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending the International Traffic in Arms Regulations to reflect current defense trade policy toward Cyprus.

DATES: This rule is effective on October 1, 2026.

FOR FURTHER INFORMATION CONTACT: Mr. Damon Smith, Foreign Affairs Officer, Office of Defense Trade Controls Policy, U.S. Department of State, telephone (202) 596–3616; email:

DDTCCustomerService@state.gov.

ATTN: Regulatory Change, ITAR Section 126.1 Cyprus Country Policy Update.

SUPPLEMENTARY INFORMATION: The Department of State (the Department) amends section 126.1 of the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120 through 130) to specify that the Republic of Cyprus' status as a proscribed destination is suspended from October 1, 2026, through September 30, 2027. This action continues the Department's current policy, which originally lifted the arms embargo to the Republic of Cyprus, under section 126.1 of the ITAR, on October 1, 2022.

Specifically, section 1250A(d) of the National Defense Authorization Act for