(ix) Tamarack Aerospace Cessna CitationJet Model 525B, 525B–0057 and 525B–0451 and ON, AFM Supplement TAG–1103–P099 CAS/AFM0002, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, September 20, 2023.

(3) For Tamarack material identified in this AD, contact Tamarack Aerospace Group, Inc., 2021 Industrial Drive, Sandpoint, ID 83864; phone: (208) 597–4568; website: *tamarackaero.com/customer-support.*

(4) You may view this material at FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. 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-locationsoremailfr.inspection@nara.gov.*

Issued on September 10, 2024.

Steven W. Thompson,

Acting Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–21112 Filed 9–16–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2024–N–4084]

Medical Devices; Immunology and Microbiology Devices; Classification of the Quantitative Viral Nucleic Acid Test for Transplant Patient Management

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the quantitative viral nucleic acid test for transplant patient management 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 the quantitative viral nucleic acid test for transplant patient management's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective September 17, 2024. The classification was applicable on July 30, 2020.

FOR FURTHER INFORMATION CONTACT: Silke Schlottmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3258, Silver Spring, MD 20993–0002, 301–796–9551, *Silke.Schlottmann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the quantitative viral nucleic acid test for transplant patient management as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

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 as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 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 (see 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 application 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 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.

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

II. De Novo Classification

On March 2, 2020, FDA received Roche Molecular Systems, Inc.'s request for De Novo classification of the cobas EBV. 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 safety and effectiveness, 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 21 U.S.C. 360c(a)(1)(B)). 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 July 30, 2020, 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 866.3183.[1] We have named the generic type of device quantitative viral nucleic acid test for transplant patient management, and it is identified as a device intended for prescription use in the detection of viral pathogens by measurement of viral deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) using specified specimen processing, amplification, and detection instrumentation. The test is intended for use as an aid in the management of transplant patients with active viral infection or at risk for developing viral infections. The test results are intended to be interpreted by qualified healthcare professionals in conjunction with other relevant clinical and laboratory findings.

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

TABLE 1—QUANTITATIVE VIRAL NUCLEIC ACID TEST FOR TRANSPLANT PATIENT MANAGEMENT RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Risk of false results	Certain warnings, limitations, results interpretation information, and explanation of procedures in labeling; and Certain device descriptions and specifications, analytical studies, clinical studies, and risk analysis in design verification and validation.
Failure to correctly interpret test results	Certain warnings, limitations, results interpretation information, and explanation of procedures in labeling.
Failure to correctly operate the device	Certain warnings, limitations, results interpretation information, and explanation of procedures in labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. 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 order. This device is 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 individually or cumulatively 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 system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

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

■ 2. Add § 866.3183 to subpart D to read as follows:

§ 866.3183 Quantitative viral nucleic acid test for transplant patient management.

(a) *Identification.* A quantitative viral nucleic acid test for transplant patient management is identified as a device intended for prescription use in the detection of viral pathogens by measurement of viral DNA or RNA using specified specimen processing, amplification, and detection instrumentation. The test is intended for use as an aid in the management of transplant patients with active viral infection or at risk for developing viral infections. The test results are intended to be interpreted by qualified healthcare professionals in conjunction with other relevant clinical and laboratory findings.

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

(1) The labeling required under § 809.10(b) of this chapter must include:

(i) A prominent statement that the device is not intended for use as a donor screening test for the presence of viral nucleic acid in blood or blood products.

(ii) Limitations which must be updated to reflect current clinical practice. These limitations must include, but are not limited to, statements that indicate:

(A) Test results are to be interpreted by qualified licensed healthcare professionals in conjunction with clinical signs and symptoms and other relevant laboratory results; and

(B) Negative test results do not preclude viral infection or tissue invasive viral disease and that test results must not be the sole basis for patient management decisions.

[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.

(iii) A detailed explanation of the interpretation of results and acceptance criteria must be provided and include specific warnings regarding the potential for variability in viral load measurement when samples are measured by different devices. Warnings must include the following statement, where applicable: ''Due to the potential for variability in [analyte] measurements across different [analyte] assays, it is recommended that the same device be used for the quantitation of [analyte] when managing individual patients.''

(iv) A detailed explanation of the principles of operation and procedures for assay performance.

(2) Design verification and validation must include the following:

(i) Detailed documentation of the device description, including all parts that make up the device, ancillary reagents required for use with the assay but not provided, an explanation of the methodology, design of the primer/probe sequences, rationale for the selected gene target, and specifications for amplicon size, guanine-cytosine content, and degree of nucleic acid sequence conservation. The design and nature of all primary, secondary and tertiary quantitation standards used for calibration must also be described.

(ii) A detailed description of the impact of any software, including software applications and hardware-based devices that incorporate software, on the device's functions;

(iii) Documentation and characterization (*e.g.,* determination of the identity, supplier, purity, and stability) of all critical reagents and protocols for maintaining product integrity throughout its labeled shelf-life.

(iv) Stability data for reagents provided with the device and indicated specimen types, in addition to the basis for the stability acceptance criteria at all time points chosen across the spectrum of the device's indicated life cycle, which must include a time point at the end of shelf life.

(v) All stability protocols, including acceptance criteria.

(vi) Final lot release criteria along with documentation of an appropriate justification that lots released at the extremes of the specifications will meet the claimed analytical and clinical performance characteristics as well as the stability claims.

(vii) Risk analysis and documentation demonstrating how risk control measures are implemented to address device system hazards, such as Failure Mode Effects Analysis and/or Hazard Analysis. This documentation must include a detailed description of a protocol (including all procedures and methods) for the continuous monitoring, identification, and handling of genetic mutations and/or novel viral stains (*e.g.,* regular review of published literature and annual in silico analysis of target sequences to detect possible primer or probe mismatches). All results of this protocol, including any findings, must be documented.

(viii) Analytical performance testing that includes:

(A) Detailed documentation of the following analytical performance studies: limit of detection, upper and lower limits of quantitation, inclusivity, precision, reproducibility, interference, cross reactivity, carry-over, quality control, specimen stability studies, and additional studies as applicable to specimen type and intended use for the device;

(B) Identification of the viral strains selected for use in analytical studies, which must be representative of clinically relevant circulating strains;

(C) Inclusivity study results obtained with a variety of viral genotypes as applicable to the specific assay target and supplemented by in silico analysis;

(D) Reproducibility studies that include the testing of three independent production lots;

(E) Documentation of calibration to a reference standard that FDA has determined is appropriate for the quantification of viral DNA or RNA (*e.g.,* a recognized consensus standard); and

(F) Documentation of traceability performed each time a new lot of the standardized reference material to which the device is traceable is released, or when the field transitions to a new standardized reference material.

(ix) Clinical performance testing that includes:

(A) Detailed documentation from either a method comparison study with a comparator that FDA has determined is appropriate, or results from a prospective clinical study demonstrating clinical validity of the device;

(B) Data from patient samples, with an acceptable number of the virus-positive samples containing an analyte concentration near the lower limit of quantitation and any clinically relevant decision points. If an acceptable number of virus-positive samples containing an analyte concentration near the lower limit of quantitation and any clinically relevant decision cannot be obtained, contrived samples may be used to supplement sample numbers when appropriate, as determined by FDA;

(C) The method comparison study must include predefined maximum acceptable differences between the test and comparator method across all primary outcome measures in the clinical study protocol; and

(D) The final release test results for each lot used in the clinical study.

Dated: September 12, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21086 Filed 9–16–24; 8:45 am]

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DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Parts 510, 525, 526, 536, 542, 544, 546, 547, 548, 549, 550, 551, 552, 553, 555, 558, 560, 562, 569, 570, 576, 578, 579, 582, 583, 584, 585, 587, 588, 589, 590, 591, 594, 598, and 599

Updating Provisions Related to Blocking and Other Actions Related to Specific Property or Interests in Property

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is adopting a final rule to clarify OFAC's process for issuing certain orders that block or identify as blocked specific property or interests in property, or that impose other prohibitions less than full blocking with respect to specific property or interests in property. OFAC is adding information about these orders in regulatory notes in 35 of OFAC's sanctions regulations.

DATES: This rule is effective September 17, 2024.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Compliance, 202–622–2490 or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *https://ofac.treasury.gov.*

Background

In this rule, OFAC is updating 35 parts of 31 CFR chapter V to clarify OFAC's processes when it issues certain