In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (n)(1) of this AD. Information may be emailed to: *AMOC@faa.gov*.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(n) Related Information

(1) For more information about this AD, contact Douglas Y. Tsuji, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3548; email: *Douglas.Tsuji@faa.gov*.

(2) Material identified in this AD that is not incorporated by reference is available at the addresses specified in paragraph (o)(3) of this AD.

(o) 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) Boeing Alert Requirements Bulletin 737–31A1880 RB, Revision 1, dated September 16, 2020.

(ii) [Reserved]

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website myboeingfleet.com.

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov*, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*.

Issued on August 1, 2024.

Peter A. White,

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

[FR Doc. 2024–21557 Filed 9–20–24; 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–2016–N–2880]

Microbiology Devices; Reclassification of Cytomegalovirus Deoxyribonucleic Acid Quantitative Assay Devices Intended for Transplant Patient Management

AGENCY: Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify cytomegalovirus (CMV) deoxyribonucleic acid (DNA) quantitative assay devices intended for transplant patient management, a postamendments class III device (product code PAB) into class II (general controls and special controls), subject to premarket notification.

DATES: This order is effective October 23, 2024.

ADDRESSES: For access to the docket to read background documents or the electronic and-written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), among other amendments, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (general controls and special controls), and class III (general controls and premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or class II or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807), subpart E, of FDA's regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

In the **Federal Register** of September 18, 2020 (85 FR 58300), FDA published a proposed order to reclassify CMV DNA quantitative assay devices intended for transplant patient management (''CMV transplant assays'') from class III into class II (general and special controls), subject to premarket notification. The comment period on the proposed order closed on November 17, 2020. FDA received two comments on the proposed order, both of which were supportive of the reclassification from Class III to Class II and agreed with FDA

that CMV transplant assays should be subject to premarket notification.

II. The Final Order

Based on the information discussed in the preamble to the proposed order (85 FR 58300), the supportive comments received on the proposed order, and FDA's experience over the years with this device type, FDA concludes that special controls, in conjunction with general controls, will provide reasonable assurance of the safety and effectiveness of CMV transplant assays. Therefore, in accordance with section 513(f)(3) of the FD&C Act, FDA is issuing this final order to reclassify CMV transplant assays from class III into class II, subject to premarket notification. This final order will be codified at 21 CFR 866.3180.[1] In this final order, FDA has identified special controls under section 513(a)(1)(B) of the FD&C Act, which in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device. FDA is reclassifying these devices and establishing the special controls as published in the proposed order without change.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device. FDA has determined that premarket notification is necessary to reasonably assure the safety and effectiveness of CMV transplant assays. Therefore, the Agency does not intend to exempt these class II devices from premarket notification (510(k)) submission as provided under section 510(m) of the FD&C Act.

The devices that are the subject of this reclassification are assigned the generic name ''quantitative CMV nucleic acid tests for transplant patient management.'' These devices are identified as a quantitative CMV nucleic acid test for transplant patient management, a device intended for prescription use in the detection of CMV and as an aid in the management of transplant patients to measure CMV DNA levels in human plasma and/or whole blood 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 CMV infection or at risk for developing CMV infection. The test results are intended to be interpreted by qualified healthcare professionals in conjunction with other relevant clinical and laboratory findings.

Under this final order, CMV transplant assays are prescription devices requiring the supervision of a practitioner licensed by law to direct the use of the devices in order to ensure accurate interpretation of results, ensuring the devices provide a reasonable assurance of safety and effectiveness. As such, the prescription device must satisfy prescription labeling requirements for in vitro diagnostic products (see 21 CFR 809.10(a)(4) and (b)(5)(ii)).

In addition, the Agency believes that certain changes could be made to CMV transplant assays that could significantly affect the safety and effectiveness of those devices and for which a new 510(k) is likely required.[2] Based on FDA's accumulated experience with these devices, changes that likely could significantly affect the safety and effectiveness of these devices include, but are not limited to, changes to critical reagents, changes to final release specifications, and changes in shelf life of the device. For more information about when to submit a new 510(k), manufacturers should refer to FDA's guidance entitled ''Deciding When to Submit at 510(k) for a Change to an Existing Device'' (Ref. 3).

III. Implementation Strategy

The order is effective 30 days after its date of publication in the **Federal Register**.

IV. 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.

V. 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. Those collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073, and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

VI. Codification of Orders

Under section 513(f)(3) of the FD&C Act, FDA may issue final orders to reclassify devices. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as newly codified orders. Therefore, under section 513(f)(3), CMV transplant assays are codified in the new 21 CFR 866.3180 under which CMV transplant assays are renamed quantitative CMV nucleic acid tests for transplant patient management and are reclassified from class III into class II.

VII. References

The following references marked with an asterisk (*) are on display in the Dockets Management Staff (see **ADDRESSES**; and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Ljungman P., M. Boeckh, H.H. Hirsch, et al., ''Definitions of CMV Infection and Disease in Transplant Patients for Use in Clinical Trials,'' *Clinical Infectious Diseases,* 64(1):87–91, 2017.
2. Singh, N. and A.P. Limaye, ''Infections in Solid-Organ Transplant Recipients,'' *Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases,* 7th Edition, Philadelphia (PA):Elsevier, pp. 3440–3452, 2015.
*3. ''Deciding When to Submit a 510(k) for a Change to an Existing Device—Guidance for Industry and Food and Drug Administration Staff,'' issued October 25, 2017 (available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM514771*).

[1] In December 2019, FDA began adding the term ''Final amendment'' to the ''ACTION'' caption for these documents, typically styled ''Final order,'' to indicate an amendment to the Code of Federal Regulations. This editorial change was made in accordance with the Office of Federal Register's 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.

[2] See 21 CFR 807.81(a)(3)(i).

*4. Transcript of the FDA Microbiology Devices Panel Meeting, November 9, 2016 (available at *https://www.fda.gov/advisory-committees/microbiology-devices-panel/2016-meeting-materials-microbiology-devices-panel*).

5. Kotton, C.N., D. Kumar, A.M. Caliendo, et al., ''Updated International Consensus Guidelines on the Management of Cytomegalovirus in Solid-Organ Transplantation,'' *Transplantation* 96(4):333–360, 2013.

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 § 866.3180 to subpart D to read as follows:

§ 866.3180 Quantitative cytomegalovirus nucleic acid tests for transplant patient management.

(a) *Identification.* A quantitative cytomegalovirus (CMV) nucleic acid test for transplant patient management is identified as a device intended for prescription use in the detection of CMV and as an aid in the management of transplant patients to measure CMV deoxyribonucleic acid (DNA) levels in human plasma and/or whole blood 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 CMV infection or at risk for developing CMV infection. 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 CMV DNA in blood or blood products.

(ii) Limitations, which must be updated to reflect current clinical practice. The 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;

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

(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 CMV 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 CMV viral load measurements across different CMV assays, it is recommended that the same device be used for the quantitation of CMV viral load when managing CMV infection in 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, reagents required for use with the CMV 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 function.

(iii) Documentation and characterization of all critical reagents (*e.g.,* determination of the identity, supplier, purity, and stability) 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 Modes 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 CMV 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, carryover, quality control, specimen stability studies, and additional studies as applicable to specimen type and intended use for the device.

(B) Identification of the CMV 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 CMV 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 standardized reference material that FDA has determined is appropriate for the quantification of CMV DNA (*e.g.,* a recognized consensus standard).

(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 of device performance data 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 CMV positive samples containing an analyte concentration near the lower limit of quantitation and any clinically relevant decision points.

(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.

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

Dated: September 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21616 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0820]

RIN 1625–AA00

Safety Zone; Kernwood Avenue Bridge Repairs—Danvers River, Salem, MA, and Beverly, MA

AGENCY: Coast Guard, DHS.

ACTION: Temporary Interim Rule and request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters at mile 1.0 Danvers River, within a 100-yard radius of the center point of the Kernwood Avenue Bridge between Salem, MA and Beverly, MA. The temporary safety zone is necessary to protect personnel, vessels and the marine environment from potential hazards created during bridge repairs. When enforced, entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Boston or a designated representative.

DATES:

Effective date: This rule is effective without actual notice from September 23, 2024 through 11:59 p.m. on December 31, 2024. For the purposes of enforcement, actual notice will be used from September 15, 2024, until September 23, 2024.

Comments due date: Comments and related material must be received by the Coast Guard on or before October 23, 2024.

ADDRESSES: You may submit comments identified by docket number USCG–2024–0820 using the Federal e-Rulemaking Portal at *http://www.regulations.gov*. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Mr. Timothy Chase, Waterways Management Division, U.S. Coast Guard Sector Boston, telephone 617–447–1620, or email *Timothy.w.chase@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
NAD 83 North American Datum 1983
§ Section
U.S.C. United States Code
MASSDOT Massachusetts Department of Transportation

II. Background Information and Regulatory History

On August 28, 2024, the Massachusetts Department of Transportation (MassDOT) bridge division notified the Waterways Management Division of U. S. Coast Guard Sector Boston that operations to make repairs to the Kernwood Avenue Bridge, spanning the Danvers River between Salem, MA, and Beverly, MA, will begin September 15, 2024.

The Coast Guard is issuing this temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the construction schedule for Kernwood Avenue Bridge was only recently finalized and prompt action is needed to respond to the potential safety hazards associated with this project. It is impracticable and contrary to the public interest to publish an NPRM because prompt action is needed to establish this safety zone by September 15, 2024, to allow for the timely repairs to the Kernwood Avenue Bridge and ensure the safety of mariners transiting the area from the dangers associated with the operations associated with these repairs.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to ensure public safety during repair operations to the Kernwood Avenue Bridge.

Although this regulation is published as an interim rule without prior notice, public comment is nevertheless desirable to ensure that the regulation is both workable and reasonable. Accordingly, persons wishing to comment may do so by submitting written comments as set out under **ADDRESSES** in this preamble. Commenters should include their names and addresses, identify the docket number for the regulation, and give reasons for their comments. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Boston (COTP) has determined that potential hazards associated with bridge repair operations starting September 15, 2024, will be a safety concern for anyone within a 100-yard radius of the center point of the Kernwood Avenue Bridge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while bridge repair operations are taking place.

IV. Discussion of Rule

This rule establishes a safety zone from September 15, 2024, through 11:59 p.m. on December 31, 2024. While the safety zone will be effective through this period, it will only be enforced during active repair operations, when work barges and cranes will be placed in the narrow navigable channel, or other instances which may create a hazard to navigation. The active repair operations will take place during the overnight hours, from 9 p.m. through 5 a.m., Sunday through Thursday, when boating traffic is minimal.

The safety zone will cover all navigable waters within a 100-yard radius of the center point of the MassDOT Kernwood Avenue Bridge, at mile 1.0, spanning the Danvers River, between Salem, MA, and Beverly, MA, in approximate position 42°32′34.8″ N 70°53′54.2″ W (NAD 83). During times of enforcement, all persons or vessels will be prohibited from entering the safety zone without permission from the COTP or a designated representative.

The Coast Guard will make notice of the safety zone via the Local Notice to Mariners and issue a Broadcast Notice to Mariners via marine channel 16 (VHF–FM) as soon as practicable in