

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2024-0470; Project Identifier AD-2023-00694-A; Amendment 39-22800; AD 2024-15-09]

RIN 2120-AA64

Airworthiness Directives; Textron Aviation Inc. (Type Certificate Previously Held by Cessna Aircraft Company) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Textron Aviation Inc. (Textron) (type certificate previously held by Cessna Aircraft Company) Model 525, 525A, and 525B airplanes with Tamarack active technology load alleviation system (ATLAS) winglets installed per Supplemental Type Certificate (STC) No. SA03842NY. This AD was prompted by a report of the potential for a failure of the ATLAS system in which a loss of load alleviation would be unannounced. This AD requires installing placards on the left-hand inboard edge of the Tamarack active camber surface (TACS) and revising the existing airplane flight manual (AFM) for your airplane. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 22, 2024.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 22, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2024-0470; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- 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](https://www.tamarackaero.com/customer-support).

- You may view this material at the 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. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2024-0470.

FOR FURTHER INFORMATION CONTACT:

Anthony Caldejon, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: (206) 231-3534; email: anthony.v.caldejon@faa.gov.

SUPPLEMENTARY INFORMATION:**Background**

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Textron (type certificate previously held by Cessna Aircraft Company) Model 525, 525A, and 525B airplanes with Tamarack ATLAS winglets installed per STC No. SA03842NY. The NPRM published in the **Federal Register** on March 22, 2024 (89 FR 20354). The NPRM was prompted by a report that while accomplishing a reliability improvement program, Tamarack discovered the potential for a failure of the ATLAS system in which a loss of load alleviation would be unannounced. The manufacturer's investigation revealed that failure of either of one of a pair of opto-isolators within the ATLAS Control Unit (ACU) can prevent an enable signal from being sent to the TACS Control Units (TCUs).

The ATLAS system is installed on Textron Model 525, 525A, and 525B airplanes under STC No. SA03842NY and lessens the increased wing loads associated with the installation of winglets. The ATLAS is designed to detect flight conditions and modify airflow at the wing tip accordingly. The ATLAS will draw power constantly to operate the logic circuit and provide power to the actuators to maintain TACS position.

The TCUs include the linear electric actuators and motor controllers that move the TACS. Since the enable signals are not monitored after the opto-isolators, the ACU cannot detect whether the generated signal is reaching the TCUs. The TCUs rely on the enable signal to determine whether to respond to commands from the ACU. If one of the opto-isolators fails, the ACU would not be able to detect that the TCUs were not enabled and the TCUs would not respond to commands from the ACU. Thus, the system would be operating in a mode of unannounced loss of load alleviation. The flight crew would be

unaware of a malfunction of the load alleviation function of ATLAS and could fly the airplane into conditions that exceed the limit load. In addition, fatigue concerns could result in cracking of the airplane's primary structure. If not addressed, this condition could result in loss of continued safe flight and landing of the airplane.

In the NPRM, the FAA proposed to require installing placards on the left-hand inboard edge of the TACS to enhance visibility of TACS movement during night operations and revising the existing AFM for your airplane to include instructions for pre-flight checks of the ATLAS system before taxi. The FAA is issuing this AD to address the unsafe condition on these products.

Discussion of Final Airworthiness Directive**Comments**

The FAA received comments from three commenters. Two of the commenters were individuals who supported the NPRM. The third commenter was Tamarack. The following presents the comments received on the NPRM from Tamarack and the FAA's response to each comment.

Request To Clarify What Prompted the NPRM

Tamarack requested that the FAA correct the SUMMARY and paragraph (e), "Unsafe Condition," which state that the NPRM was prompted by a report of an unannounced failure of the ATLAS system. Tamarack commented that this statement is not accurate because even though Tamarack reported the design deficiency to the FAA under 14 CFR 21.3, "Reporting of failures, malfunctions, and defects," there had not been any actual failures of the ATLAS system in the fleet. Tamarack stated that the "Background" section of the NPRM more accurately explains that, while accomplishing a reliability improvement program, Tamarack discovered the potential for a failure of the ATLAS system in which a loss of load alleviation would be unannounced.

The FAA agrees to correct the language identified by the commenter and has revised the SUMMARY and paragraph (e) of this AD accordingly.

Request To Revise "Proposed AD Requirements in This NPRM" Section

Tamarack requested that the FAA revise the "Proposed AD Requirements in This NPRM" section of the NPRM to specify who can accomplish the required actions. Tamarack stated that it is unclear whether a pilot can install the

placards on the left-hand inboard edge of the TACS or whether the placards must be installed by a certificated airframe and powerplant (A&P) mechanic.

Paragraph (g) of this AD only allows a pilot to do the revision to the AFM required by paragraph (g)(2) of this AD and does not allow a pilot to do the installation of placards required by paragraph (g)(1) of this AD. An FAA-certificated A&P mechanic or repair station must install the placards on the left-hand inboard edge of the TACS. The FAA has not revised the “Proposed AD Requirements in This NPRM” section as requested by the commenter because that section of the NPRM is not carried over into this final rule.

Request To Revise “FAA’s Determination” Section of the NPRM

Tamarack requested that the FAA revise the “FAA’s Determination” section of the NPRM, which states that the FAA has determined that the unsafe condition is likely to exist or develop on other products of the same type design. Tamarack stated that the probability of the unsafe condition is “remote” and not “likely” and therefore using “likely” misrepresents the probability of the identified unsafe condition occurring in the fleet.

The FAA disagrees. The “FAA’s Determination” section of the NPRM correlates to the FAA’s finding under 14 CFR 39.5, which states the conditions that must be present when the FAA issues an AD. If an unsafe condition only exists on one product and is not likely to exist or develop on other products of the same type design, or if there are no other existing products of the same type design, the FAA will accomplish corrective action through means other than an AD. The FAA’s finding under 14 CFR 39.5 is unrelated to the probability of the failure condition described by the commenter.

The FAA did not revise this final rule regarding this issue.

Conclusion

The FAA reviewed the relevant data, considered any comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on these products. Except for the change described previously, this AD is adopted as proposed in the NPRM.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Tamarack Aerospace Atlas Service Bulletin SBATLAS-57-06, Issue A, dated April 19, 2023. This material specifies procedures for installing placards on the left-hand inboard edge of the TACS to enhance visibility of TACS movement during night operations.

The FAA also reviewed the following AFM supplements, which contain, among other items, instructions for pre-flight checks of the ATLAS system before taxi. These documents are distinct because they apply to different airplane models.

- Tamarack Aerospace Cessna Citation Model 525, 525-0001 thru -0359, AFM Supplement TAG-1101-0099 CA/DD/M023, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, dated September 20, 2023.
- Tamarack Aerospace Cessna Citation Model 525, 525-0360 through -0599, AFM Supplement TAG-1101-1099 CA/DD/M037, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, dated September 20, 2023.
- Tamarack Aerospace Cessna Citation Model 525, 525-0600 through -0684 and -0686 through -0701, AFM Supplement TAG-1101-P099 CA/DD/M038, Tamarack Active Technology Load Alleviation System (Atlas)

Winglets, Issue D, dated September 20, 2023.

- Tamarack Aerospace Cessna Citation Model 525, 525-0685 and -0800 and on, AFM Supplement TAG-1101-M099 CA/DD/M088, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, September 20, 2023.
- Tamarack Aerospace Cessna Citation Model 525A, 525A-0001 thru -0299, AFM Supplement TAG-1102-0099 CAS/AFM0003, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, September 20, 2023.
- Tamarack Aerospace Cessna Citation Model 525A, 525A-0300 and on, AFM Supplement TAG-1102-P099 CAS/AFM0004, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, September 20, 2023.
- Tamarack Aerospace Cessna Citation Jet Model 525B, 525B-0001 thru 525B-0056 and 525B-0058 thru 525B-0450, AFM Supplement TAG-1103-0099 CAS/AFM0001, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, September 20, 2023.
- Tamarack Aerospace Cessna Citation Jet 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.

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

The FAA estimates that this AD affects 148 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Install placards	0.5 work-hour × \$85 per hour = \$42.50	\$20	\$62.50	\$9,250
Revise AFM	1 work-hour × \$85 per hour = \$85	0	85	12,580

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more

detail the scope of the Agency’s authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil

aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or

develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Will not affect intrastate aviation in Alaska, and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2024–15–09 Textron Aviation Inc. (Type Certificate Previously Held by Cessna Aircraft Company): Amendment 39–22800; Docket No. FAA–2024–0470; Project Identifier AD–2023–00694–A.

(a) Effective Date

This airworthiness directive (AD) is effective October 22, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Textron Aviation Inc. (type certificate previously held by Cessna Aircraft Company) Model 525, 525A, and 525B airplanes, all serial numbers (S/Ns), certificated in any category, with Tamarack active technology load alleviation system (ATLAS) winglets installed in accordance with Supplemental Type Certificate No. SA03842NY.

(d) Subject

Joint Aircraft System Component (JASC) Code 2770, Gust Lock/Damper System

(e) Unsafe Condition

This AD was prompted by a report of the potential for a failure of the ATLAS system in which a loss of load alleviation would be un-annunciated. The FAA is issuing this AD to address un-annunciated loss of load alleviation which, if not addressed, could lead to the flight crew flying the airplane into conditions that exceed the limit load, as well as fatigue cracking in the airplane’s primary

structure. This could result in loss of continued safe flight and landing of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Within 60 hours time-in-service or 6 months after the effective date of this AD, whichever occurs first, do the actions required by paragraphs (g)(1) and (2) of this AD.

(1) Install placards on the left-hand Tamarack active camber surface (TACS) in accordance with steps 1 through 3 of the Accomplishment Instructions in Tamarack Aerospace Atlas Service Bulletin SBATLAS–57–06, Issue A, dated April 19, 2023.

(2) Revise the Normal Procedures section of the existing airplane flight manual (AFM) for your airplane by adding the information in Figure 1 to paragraph (g)(2) of this AD under “Before Taxi” or by incorporating the AFM supplement applicable to your airplane identified in Figure 2 to paragraph (g)(2) of this AD. Using a different document with information identical to this information under “Before Taxi” in the AFM for your airplane is acceptable for compliance with the requirements of this paragraph. The owner/operator (pilot) holding at least a private pilot certificate may revise the existing AFM for your airplane and must enter compliance with the applicable paragraph of this AD into the airplane maintenance records in accordance with 14 CFR 43.9(a) and 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

FIGURE 1 TO PARAGRAPH (g)(2)—ATLAS CHECK PROCEDURE

Before Taxi	
WARNING	
The TACS should move rapidly and forcefully trailing edge up and return to the neutral position when the ATLAS first receives power. Be sure that all personnel and equipment are clear before moving switch to the ON position.	
ATLAS System	CHECK
(Test that the ATLAS is working properly.)	
a. In poor light or dark conditions, turn on left side reading light.	
b. In poor light or dark conditions, turn on Wing Inspection Light.	
c. ATLAS INOP Button—Press 3 times within 3 seconds. ATLAS INOP Button light will flash 3 times when system goes through BIT (Built In Test).	
WARNING	
The TACS should move rapidly and forcefully trailing edge up and return to the neutral position when running the BIT function. Be sure that all personnel and equipment are clear before pressing.	
d. TACS	CHECK MOVEMENT
Both TACS should rapidly move up and return to the neutral position.	
i. If the TACS do not move after completing step c., this may indicate that ATLAS is not functioning normally.	
ii. Refer to Abnormal Procedure ATLAS INOPERATIVE ON THE GROUND (TACS DO NOT MOVE IN BIT).	
e. Wait approximately 10 seconds.	
f. ATLAS INOP Button light	CHECK OFF
g. If left side reading light is illuminated, turn off at pilot’s discretion.	
h. If Wing Inspection Light is illuminated, turn off at pilot’s discretion.	
NOTE	
If annunciator remains illuminated, or if the TACS do not move, a fault has been identified in the system. In either case refer to Abnormal Procedures ATLAS INOPERATIVE ON THE GROUND.	

FIGURE 2 TO PARAGRAPH (g)(2)—TAMARACK ATLAS AFM SUPPLEMENTS

Model and S/N	Tamarack ATLAS AFM supplement
Model 525, S/Ns 525–0001 through 525–0359 inclusive	Paragraph 3A, ATLAS System, under “Before Taxiing” in the Normal Procedures section of Cessna Citation Model 525, 525–0001 thru –0359, AFM Supplement TAG–1101–0099 CA/DD/M023, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, dated September 20, 2023.
Model 525, S/Ns 525–0360 through 525–0599 inclusive	Paragraph 3A, ATLAS System, under “Before Taxi” in the Normal Procedures section of Cessna Citation Model 525, 525–0360 thru –0599, AFM Supplement TAG–1101–1099 CA/DD/M037, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, dated September 20, 2023.
Model 525, S/Ns 525–0600 through 525–0684 inclusive and S/Ns 525–0686 through 525–0701 inclusive.	Paragraph 1A, ATLAS System, under “Before Taxi” in the Normal Procedures section of Cessna Citation Model 525, 525–0600 through –0684 and –0686 through –0701, AFM Supplement TAG–1101–P099 CA/DD/M038, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, dated September 20, 2023.
Model 525, S/N 525–0685 and S/Ns 525–0800 and larger	Paragraph 9A, ATLAS System, under “Before Taxi” in the Normal Procedures section of Cessna Citation Model 525, 525–0685 and –0800 and on, AFM Supplement TAG–1101–M099 CA/DD/M088, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, dated September 20, 2023.
Model 525A, S/Ns 525A–0001 through 525–0299 inclusive	Paragraph 3A, ATLAS System, under “Before Taxi” in the Normal Procedures section of Cessna Citation Model 525A, 525A–0001 thru –0299, AFM Supplement TAG–1102–0099 CAS/AFM0003, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, dated September 20, 2023.
Model 525A, S/Ns 525A–0300 and larger	Paragraph 1A, ATLAS System, under “Before Taxi” in the Normal Procedures section of Cessna Citation Model 525A, 525A–0300 and on, AFM Supplement TAG–1102–P099 CAS/AFM0004, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, dated September 20, 2023.
Model 525B, S/Ns 525B–0001 through 525B–0056 inclusive and S/Ns 525B–0058 through 525B–0450 inclusive.	Paragraph 1A, ATLAS System, under “Before Taxi” in the Normal Procedures section of Cessna CitationJet Model 525B, 525B–0001 thru 525B–0056 and 525B–0058 thru 525B–0450, AFM Supplement TAG–1103–0099 CAS/AFM0001, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, dated September 20, 2023.
Model 525B, S/N 525B–0057 and S/Ns 525B–0451 and larger	Paragraph 9A, ATLAS System, under “Before Taxi” in the Normal Procedures section of 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, dated September 20, 2023.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, West Certification 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 West Certification Branch, send it to the attention of the person identified in paragraph (i) of this AD and email it to 9-ANM-Seattle-ACO-AMOC-Requests@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.

(i) Related Information

For more information about this AD, contact Anthony Caldejon, Aviation Safety Engineer, FAA, 3960 Paramount Boulevard, Lakewood, CA 90712; phone: (206) 231–3534; email: anthony.v.caldejon@faa.gov.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) Tamarack Aerospace Atlas Service Bulletin SBATLAS–57–06, Issue A, dated April 19, 2023.

(ii) Tamarack Aerospace Cessna Citation Model 525, 525–0001 thru –0359, Airplane Flight Manual (AFM) Supplement TAG–1101–0099 CA/DD/M023, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, dated September 20, 2023.

(iii) Tamarack Aerospace Cessna Citation Model 525, 525–0360 thru –0599, AFM Supplement TAG–1101–1099 CA/DD/M037, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, dated September 20, 2023.

(iv) Tamarack Aerospace Cessna Citation Model 525, 525–0600 through –0684 and –0686 through –0701, AFM Supplement TAG–1101–P099 CA/DD/M038, Tamarack Active Technology Load Alleviation System

(Atlas) Winglets, Issue D, dated September 20, 2023.

(v) Tamarack Aerospace Cessna Citation Model 525, 525–0685 and –0800 and on, AFM Supplement TAG–1101–M099 CA/DD/M088, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue D, September 20, 2023.

(vi) Tamarack Aerospace Cessna Citation Model 525A, 525A–0001 thru –0299, AFM Supplement TAG–1102–0099 CAS/AFM0003, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, September 20, 2023.

(vii) Tamarack Aerospace Cessna Citation Model 525A, 525A–0300 and on, AFM Supplement TAG–1102–P099 CAS/AFM0004, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, September 20, 2023.

(viii) Tamarack Aerospace Cessna CitationJet Model 525B, 525B–0001 thru 525B–0056 and 525B–0058 thru 525B–0450, AFM Supplement TAG–1103–0099 CAS/AFM0001, Tamarack Active Technology Load Alleviation System (Atlas) Winglets, Issue C, September 20, 2023.

(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