

**§ 29.3 Procedures for filing, hearing, and determination of applications.**

(a) *Time and place of filing.*  
Applications for the extension of tobacco inspection to new markets and to additional sales on designated markets shall be filed with the Hearing Clerk not later than September 15 in the case of flue-cured tobacco, December 1 in the case of Maryland tobacco, and July 15 in the case of burley and all other kinds of tobacco. Applications should be addressed to the Office of the Hearing Clerk, United States Department of Agriculture, 1400 Independence Ave. SW, Stop 9203, Room 1031, South Building, Washington, DC 20250–9203. Applications which are not received by the Hearing Clerk on or before the foregoing cutoff date for the kind of tobacco shall be rejected as untimely filed. After denial of an application for additional inspection services for a marketing season, no application from the same auction market or proposed new market shall be considered for the next consecutive marketing season, unless the application contains a statement by the applicant setting forth new facts that constitute evidence of such a substantial change in conditions since the previous hearing as the review committee as specified in paragraph (h) of this section deems would warrant such further hearing.

\* \* \* \* \*

(c) *Hearings on applications.*  
Following the closing date for filing applications for each kind of tobacco, a hearing or hearings shall be held on the applications, if any, filed for additional inspection services for the kind of tobacco in question. Such hearing or hearings shall be scheduled to begin within 60 days following the closing date for such applications. Notice of hearing shall be issued by the Secretary, filed with the Hearing Clerk, and published in the **Federal Register**, and a copy shall be mailed by the Hearing Clerk to each applicant. Such publication and mailing shall be not less than 5 days prior to the opening of the hearing.

\* \* \* \* \*

**Subpart G—Policy Statement and Provisions Governing the Availability of Tobacco Inspection Services to Flue-Cured Tobacco**

- 7. Revise the heading to subpart G to read as set forth above.
- 8. Remove the authority citation to subpart G.

**§ 29.9402 [Amended]**

- 9. Amend § 29.9402 by removing the phrase “or the extension of price support to producers” in the first sentence.

**§ 29.9406 [Amended]**

- 10. Amend § 29.9406, in paragraph (b), by removing the phrase “or price support services” in the first sentence.

**Bruce Summers,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 2025–09552 Filed 5–29–25; 8:45 am]

**BILLING CODE 3410–02–P**

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

[Docket No. FAA–2025–0920; Project Identifier MCAI–2025–00933–T; Amendment 39–23052; AD 2025–11–06]

**RIN 2120–AA64**

**Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; request for comments.

**SUMMARY:** The FAA is superseding Airworthiness Directive (AD) 2025–07–04, which applied to all Airbus Canada Limited Partnership Model BD–500–1A11 airplanes. AD 2025–07–04 required a review and disposition of all existing repairs and damage assessments for affected structure, corrective actions if necessary, and the prohibition of certain repair engineering orders (REOs). Since the FAA issued AD 2025–07–04, the FAA determined that the list of acceptable generic repair engineering orders (GREOs) specified in table 1 to paragraph (h)(3) of AD 2025–07–04 was added in error. This AD continues to require review and disposition of all existing repairs and damage assessments for affected structure, which includes GREOs that were identified in AD 2025–07–04, corrective actions if necessary, and the prohibition of certain REOs. The FAA is issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective June 16, 2025.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD

as of May 27, 2025 (90 FR 16791, April 22, 2025).

The FAA must receive comments on this AD by July 14, 2025.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to [regulations.gov](https://www.regulations.gov). Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

*AD Docket:* You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–0920; 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, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

*Material Incorporated by Reference:*

- For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email [TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca](mailto:TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca); website at [tc.canada.ca/en/aviation](https://tc.canada.ca/en/aviation).

- For Airbus Canada material identified in this AD, contact Airbus Canada Limited Partnership, 13100 Henri-Fabre Boulevard, Mirabel, Québec J7N 3C6, Canada; telephone 450–476–7676; email [a220\\_crc@abc.airbus](mailto:a220_crc@abc.airbus); website [a220world.airbus.com](https://a220world.airbus.com).

- 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. It is also available at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2025–0920.

**FOR FURTHER INFORMATION CONTACT:**

Stefanie Roesli, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3964; email: [Stefanie.N.Roesli@faa.gov](mailto:Stefanie.N.Roesli@faa.gov).

**SUPPLEMENTARY INFORMATION:****Comments Invited**

The FAA invites you to send any written data, views, or arguments about

this final rule. Send your comments using a method listed under the **ADDRESSES** section. Include “Docket No. FAA–2025–0920; Project Identifier MCAI–2025–00933–T” at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *regulations.gov*, including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

#### Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as “PROPIN.” The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Stefanie Roesli, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3964; email: [Stefanie.N.Roesli@faa.gov](mailto:Stefanie.N.Roesli@faa.gov). Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

#### Background

The FAA issued AD 2025–07–04, Amendment 39–23005 (90 FR 16791, April 22, 2025) (AD 2025–07–04), for all Airbus Canada Limited Partnership Model BD–500–1A11 airplanes. AD 2025–07–04 was prompted by an MCAI originated by Transport Canada, which is the aviation authority for Canada. Transport Canada issued AD CF–2023–70, dated October 5, 2023 (Transport Canada AD CF–2023–70), to correct an unsafe condition.

AD 2025–07–04 required a review and disposition of all existing repairs and damage assessments for affected structure, corrective actions if necessary, and the prohibition of certain REOs. The FAA issued AD 2025–07–04 to address in-service repairs in some structural areas that require verification and possibly further repair. The unsafe condition, if not addressed, could result in negative margins for the load envelopes.

#### Actions Since AD 2025–07–04 Was Issued

Since the FAA issued AD 2025–07–04, the FAA determined that the list of acceptable GREOs specified in table 1 to paragraph (h)(3) of AD 2025–07–04 was added in error. In the final rule for AD 2025–07–04, the FAA added paragraph (h)(3) to that AD to identify GREOs that were acceptable to comply with the intent of the AD and identified GREOs issued prior to September 22, 2022, as acceptable. However, those identified GREOs are the ones that are deactivated and are not acceptable since they require reassessment to the new loads. Only GREOs with an issue date later than September 22, 2022, have been validated by Airbus and are acceptable for use and therefore do not require reassessment to the new loads.

The FAA has revised paragraph (h)(3) of this AD to remove the reference to table 1 to paragraph (h)(3), which listed GREOs issued prior to September 22, 2022, and instead identifies GREOs with an issue date later than September 22, 2022, as those that have already been validated and therefore do not require an additional approved disposition.

The FAA is issuing this AD to address the unsafe condition on these products. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2025–0920.

#### Material Incorporated by Reference Under 1 CFR Part 51

This AD requires Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 001, dated September 13, 2023; and Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 002, dated March 6, 2024; and Transport Canada AD CF–2023–70, dated October 5, 2023; which the Director of the Federal Register approved for incorporation by reference as of May 27, 2025 (90 FR 16791, April 22, 2025). 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.

#### FAA’s Determination

These products have been approved by the civil aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA’s bilateral agreement with this State of Design Authority, that authority has notified the FAA of the unsafe condition described in the MCAI and material referenced above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

#### Requirements of This AD

This AD retains all requirements of AD 2025–07–04, except it removes the list of GREOs specified in table 1 to paragraph (h)(3) of AD 2025–07–04 that were added in error and must be reassessed. This AD requires a review and disposition of all existing repairs and damage assessments for affected structure, corrective actions if necessary, and the prohibition of certain REOs.

#### Explanation of Required Compliance Information

In the FAA’s ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the incorporation by reference of Transport Canada AD CF–2023–70 is retained. This AD requires compliance with Transport Canada AD CF–2023–70 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Material required by Transport Canada AD CF–2023–70 for compliance will be available at *regulations.gov* under Docket No. FAA–2025–0920 after this AD is published.

#### FAA’s Justification and Determination of the Effective Date

Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for “good cause,” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to

make rules effective in less than thirty days, upon a finding of good cause.

The FAA determined that the list of acceptable GREOs specified in table 1 to paragraph (h)(3) of AD 2025–07–04, which is effective May 27, 2025, was added in error. Instead of specifying only GREOs issued later than September 22, 2022, which are acceptable, the list of GREOs in table 1 included those issued before September 22, 2022, which have not been validated and are not acceptable. Therefore, the FAA is superseding AD 2025–07–04 to correct

this error and ensure deactivated GREOs are reassessed. Accordingly, notice and opportunity for prior public comment are impractical and unnecessary, pursuant to 5 U.S.C. 553(b).

In addition, for the foregoing reason(s), the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

#### Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause

pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

#### Costs of Compliance

The FAA estimates that this AD affects 71 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

#### ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × \$85 per hour = \$170 .....	\$0	\$170	\$12,070

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this AD.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

#### 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, and
- (2) Will not affect intrastate aviation in Alaska.

#### 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:
- a. Removing Airworthiness Directive (AD) 2025–07–04, Amendment 39–23005 (90 FR 16791, April 22, 2025); and
  - b. Adding the following new AD:

**2025–11–06 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–23052; Docket No. FAA–2025–0920; Project Identifier MCAI–2025–00933–T.**

##### (a) Effective Date

This airworthiness directive (AD) is effective June 16, 2025.

##### (b) Affected ADs

This AD replaces AD 2025–07–04, Amendment 39–23005 (90 FR 16791, April 22, 2025) (AD 2025–07–04).

#### (c) Applicability

This AD applies to all Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A11 airplanes, certificated in any category.

#### (d) Subject

Air Transport Association (ATA) of America Code 51, Standard practices/structures.

#### (e) Unsafe Condition

This AD was prompted by a design review of aircraft structural and stress reports that resulted in a revision of operational loads for some aircraft flight phases, affecting certain aircraft sections. The FAA is issuing this AD to address in-service repairs in some structural areas that require verification and possibly further repair. The unsafe condition, if not addressed, could result in negative margins for the load envelopes.

#### (f) Compliance

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

#### (g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2023–70, dated October 5, 2023 (Transport Canada AD CF–2023–70).

#### (h) Exceptions to Transport Canada AD CF–2023–70

(1) Where Transport Canada AD CF–2023–70 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where the definition of “Affected Structure” in Transport Canada AD CF–2023–70 specifies “as identified in Service Bulletin (SB) BD500–530012, Issue 001, dated 13 September 2023 or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada”, this AD requires replacing that text with “as identified in Airbus Canada Limited Partnership Service Bulletin BD500–530012,

Issue 001, dated September 13, 2023; or Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 002, dated March 6, 2024”.

(3) Where paragraph 1.2.1 of Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 001, dated September 13, 2023, specifies “Airbus Canada specific Repair Engineering Order (REO) with an issue date later than December 31, 2022 have already been validated and therefore do not require an additional approved disposition”, and where paragraph 1.2.1 of Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 002, dated March 6, 2024, specifies “Airbus Canada specific Repair Engineering Orders (REO) with an issue date later than December 31, 2022 have already been validated and therefore do not require an additional approved disposition”, this AD requires replacing that text with “Airbus Canada specific Repair Engineering Orders (REOs) with an issue date later than December 31, 2022, and Generic Repair Engineering Orders (GREOs) with an issue date later than September 22, 2022, have already been validated and therefore do not require an additional approved disposition”.

#### (i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: AIR–520, Continued Operational Safety Branch, 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 responsible Flight Standards 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 (j) of this AD and email to: [AMOC@faa.gov](mailto:AMOC@faa.gov). Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, AIR–520, Continued Operational Safety Branch, FAA; or Transport Canada; or Airbus Canada Limited Partnership’s Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

#### (j) Additional Information

For more information about this AD, contact Stefanie Roesli, Aviation Safety Engineer, FAA, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3964; email: [Stefanie.N.Roesli@faa.gov](mailto:Stefanie.N.Roesli@faa.gov).

#### (k) 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 this AD specifies otherwise.

(3) The following material was approved for IBR on May 27, 2025 (90 FR 16791, April 22, 2025).

(i) Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 001, dated September 13, 2023.

(ii) Airbus Canada Limited Partnership Service Bulletin BD500–530012, Issue 002, dated March 6, 2024.

(iii) Transport Canada AD CF–2023–70, dated October 5, 2023.

(4) For Airbus Canada material identified in this AD, contact Airbus Canada Limited Partnership, 13100 Henri-Fabre Boulevard, Mirabel, Québec J7N 3C6, Canada; telephone 450–476–7676; email [a220\\_website@a220world.airbus.com](mailto:a220_website@a220world.airbus.com).

(5) For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email [TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca](mailto:TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca); website [tc.canada.ca/en/aviation](http://tc.canada.ca/en/aviation).

(6) 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.

(7) 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](http://www.archives.gov/federal-register/cfr/ibr-locations) or email [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov).

Issued on May 23, 2025.

**Lona C. Saccomando,**

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

[FR Doc. 2025–09769 Filed 5–27–25; 11:15 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 862

[Docket No. FDA–2025–N–1281]

### Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Anti-Mullerian Hormone Test System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is classifying the anti-mullerian hormone test system 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 anti-mullerian hormone test system’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, in part by reducing regulatory burdens.

**DATES:** This order is effective May 30, 2025. The classification was applicable on December 19, 2016.

#### FOR FURTHER INFORMATION CONTACT:

Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993–0002, 240–402–6357, [Ryan.Lubert@fda.hhs.gov](mailto:Ryan.Lubert@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the anti-mullerian hormone test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. 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 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