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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0109; Product Identifier 2018–NM–022–AD; Amendment 39–19196; AD 2018–04–01]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus Model A320–271N, A321–271N, and A321–272N airplanes. This AD requires de-pairing certain International Aero Engines (IAE) engines in order to continue to operate affected airplanes and discontinuing extended operations (ETOPS) for airplanes with at least one affected engine. This AD was prompted by reports of two engine in-flight shutdowns (IFSDs) and two rejected takeoffs. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective February 15, 2018.

We must receive comments on this AD by April 2, 2018.

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 *http://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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0109; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057–3356; telephone: 425–227–1405; fax: 425–227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Emergency Airworthiness Directive 2018–0041–E, dated February 9, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for Airbus Model A320–271N, A321–271N, and A321–272N airplanes, with certain IAE engines. The MCAI states:

> Several occurrences of engine in-flight shut-down (IFSD) and Rejected Take-Off (RTO) have been reported on certain Airbus A320neo family aeroplanes. While investigation is ongoing to determine the root cause, preliminary findings indicate that the affected engines, which have high pressure compressor aft hub modification embodied from ESN P770450, are more susceptible to IFSD.
>
> This condition, if not corrected, could lead to dual engine IFSD.
>
> To address this potentially unsafe condition, Airbus issued Alert Operators Transmission (AOT) A71N014–18, providing instructions to de-pair the affected engines and discontinue Extended range Two-engine aeroplanes Operations (ETOPS) for aircraft fitted with affected engines.
>
> For the reasons described above, this [EASA] AD requires implementation of operational restrictions.
>
> This [EASA] AD is considered to be an interim action and further AD action may follow.

The unsafe condition is a high-pressure compressor (HPC) rear hub knife edge seal fracture, which could lead to a sudden increase in high rotor vibration and stall in certain IAE PW1100G–JM engines, and consequent IFSDs and rejected takeoffs. You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0109.

FAA's Determination and Requirements of This AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI. We are issuing this AD because we evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because of an unacceptable rate of IFSDs and rejected takeoffs on affected airplanes. Therefore, we determined that notice and opportunity for public comment before issuing this AD are impracticable. In addition, for the reasons stated above we find that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite you to send any written relevant data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0109;

Product Identifier 2018–NM–022–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this AD.

Costs of Compliance

We estimate that this AD affects 8 airplanes of U.S. registry.

We recognize that this AD may impose certain operational costs. However, we cannot calculate those costs because we do not know how often the conditions occur. Continued operational safety makes these costs necessary because of the severity of the unsafe condition.

If an operator chooses to replace an affected engine, we estimate it would take 8 work-hours, at $85 per hour, or $680 per product.

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.

We are 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

We determined that 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. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska; and

4. 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.

Adoption of 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 (AD):

2018–04–01 Airbus: Amendment 39–19196; Docket No. FAA–2018–0109; Product Identifier 2018–NM–022–AD.

(a) Effective Date

This AD becomes effective February 15, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A320–271N, A321–271N, and A321–272N airplanes, certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 72, Engine.

(e) Reason

This AD was prompted by reports of two engine in-flight shutdowns (IFSDs) and two rejected takeoffs. We are issuing this AD to address a high-pressure compressor (HPC) rear hub knife edge seal fracture, which could lead to a sudden increase in high rotor vibration and stall in certain PW1100G–JM engines, and consequent IFSDs or rejected takeoffs.

(f) Compliance

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

(g) Affected Engines

For the purpose of this AD, affected engines are International Aero Engines Model PW1127G–JM, PW1127GA–JM, PW1130G–JM, PW1133G–JM, and PW1133GA–JM engines, having engine serial numbers P770450 and subsequent.

(h) Operational Restrictions

(1) No later than 3 flight cycles after the effective date of this AD, do not operate an airplane having two affected engines installed.

(2) For an airplane having at least one affected engine installed: No later than 1 flight cycle after the effective date of this AD, extended operations (ETOPS) are not allowed.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to *9-ANM-116-AMOC-REQUESTS@faa.gov*. 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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA emergency Airworthiness Directive 2018–0041–E, dated February 9, 2018, for related information. You may examine the MCAI on the internet at *http://www.regulations.gov* by

searching for and locating Docket No. FAA–2018–0109.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057–3356; telephone: 425–227–1405; fax: 425–227–1149.

(k) Material Incorporated by Reference

None.

Issued in Renton, Washington, on February 12, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–03185 Filed 2–14–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2018–N–0370]

Medical Devices; General and Plastic Surgery Devices; Classification of the Non-Absorbable, Hemostatic Gauze for Temporary Internal Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the non-absorbable, hemostatic gauze for temporary internal use 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 non-absorbable, hemostatic gauze for temporary internal use'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 February 15, 2018. The classification was applicable on June 30, 2017.

FOR FURTHER INFORMATION CONTACT: Peter Hudson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G434, Silver Spring, MD 20993–0002, 301–796–6440, *peter.hudson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the non-absorbable, hemostatic gauze for temporary internal use 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 to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

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. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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 shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 16, 2016, Z-Medica, LLC, submitted a request for De Novo classification of the D2 Dressing. 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 June 30, 2017, FDA issued an order to the requester