

Type Certification Basis

Under the provisions of 14 CFR 21.17, Bombardier Inc. must show that the Model BD-700-2A12 and BD-700-2A13 airplanes meet the applicable provisions of part 25 as amended by Amendments 25-1 through 25-129.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model BD-700-2A12 and BD-700-2A13 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Model BD-700-2A12 and BD-700-2A13 airplanes must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36; and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92-574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Bombardier Model BD-700-2A12 and BD-700-2A13 airplanes will incorporate the following novel or unusual design feature:

An electronic flight-control system that contains fly-by-wire control laws, including envelope protections, for high-speed protection functions. Current part 25 requirements do not contain appropriate standards for high-speed protection systems.

Discussion

Model BD-700-2A12 and BD-700-2A13 airplanes are equipped with a high-speed protection system, which, when the system detects airspeed exceeding a small tolerance above V_{MO}/M_{MO} , employs a high-speed limiter to automatically deploy multifunction spoilers (MFS) as speed brakes. The MFS retract automatically when the system detects that airspeed is sufficiently reduced.

These special conditions contain the additional safety standards that the

Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Bombardier Model BD-700-2A12 and BD-700-2A13 airplanes. Should Bombardier Inc. apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on Bombardier Model BD-700-2A12 and BD-700-2A13 airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, because a delay would significantly affect the certification of the airplane, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Bombardier Model BD-700-2A12 and BD-700-2A13 airplanes. The requirements of § 25.253 (high-speed characteristics), and its related policy, are applicable to the Model BD-700-2A12 and BD-700-2A13 airplanes, and are not affected by these special conditions.

In addition to § 25.143, the following requirement applies:

Operation of the high-speed limiter during all routine and descent procedure flight must not impede normal attainment of speeds up to high-speed warning.

Issued in Renton, Washington, on August 7, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. FAA-2015-0311; Special Conditions No. 25-592-SC]

Special Conditions: Gulfstream Aerospace Corporation Model GVII-G500 Airplanes; Electronic Flight Control System: Control Surface Position Awareness

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions, request for comments.

SUMMARY: These special conditions are issued for Gulfstream Model GVII-G500 airplanes. These airplanes have a novel or unusual design feature associated with control-surface awareness provided by the electronic flight-control system. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: This action is effective on Gulfstream on August 18, 2015. We must receive your comments by October 2, 2015.

ADDRESSES: Send comments identified by docket number FAA-2015-0311 using any of the following methods:

- **Federal eRegulations Portal:** Go to <http://www.regulations.gov/> and follow the online instructions for sending your comments electronically.

- **Mail:** Send comments to Docket Operations, M-30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- **Hand Delivery or Courier:** Take comments to Docket Operations in Room W12-140 of the West Building

Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- **Fax:** Fax comments to Docket Operations at 202-493-2251.

Privacy: The FAA will post all comments it receives, without change, to <http://www.regulations.gov/>, including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477-19478), as well as at <http://DocketsInfo.dot.gov/>.

Docket: Background documents or comments received may be read at <http://www.regulations.gov/> at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joe Jacobsen, FAA, Airplane and Flightcrew Interface Branch, ANM-111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057-3356; telephone (425) 227-2011; facsimile (425) 227-1320.

SUPPLEMENTARY INFORMATION: The FAA has determined that notice of, and opportunity for prior public comment on, these special conditions is impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected airplanes.

In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

Background

On March 29, 2012, Gulfstream applied for a type certificate for their new Model GVII-G500 airplane. This airplane is a large-cabin business jet capable of accommodating up to 19 passengers. It will incorporate a low, swept-wing design with winglets and a T-tail. The powerplant will consist of two aft-fuselage mounted Pratt &

Whitney turbofan engines. Avionics will include four primary display units and multiple touchscreen controllers. The flight-control system is a three-axis, fly-by-wire system controlled through active control/coupled side sticks.

The Model GVII-G500 airplane will have a wingspan of approximately 87 ft. and a length of just over 91 ft. Maximum takeoff weight will be approximately 76,850 lbs and maximum takeoff thrust will be approximately 15,135 lbs. Maximum range will be approximately 5,000 nm and maximum operating altitude will be 51,000 ft.

In airplanes with electronic flight-control systems, a direct correspondence between pilot-control position and the associated airplane control-surface position is not always apparent. Under certain circumstances, a commanded maneuver that may not involve a large flightcrew-control input may nevertheless require a large control-surface movement to accomplish, possibly encroaching on a control-surface or actuation-system limit without the flightcrew's knowledge. This situation can arise in both piloted (*i.e.*, manual) and autopilot flight, and may be further intensified on airplanes where the pilot controls are not back-driven during autopilot system operation.

These special conditions for control-surface awareness, applicable to Gulfstream Model GVII-G500 airplanes, require suitable flight-control-position annunciation and control-system mode of operation to be provided to the flightcrew when a flight condition exists in which nearly full surface authority (not crew-commanded) is being utilized. Suitability of such a display must take into account that some pilot-demanded maneuvers (*e.g.*, rapid roll) are necessarily associated with intended full performance, which may saturate the surface. Therefore, simple alerting systems, which would function in both intended or unexpected control-limiting situations, must be properly balanced between needed crew awareness and nuisance features. A monitoring system that might compare airplane motion, surface deflection, and pilot side-stick controller (SSC) demand, could be useful for elimination of nuisance alerting.

Type Certification Basis

Under Title 14, Code of Federal Regulations (14 CFR) 21.17, Gulfstream must show that the Model GVII-G500 airplane meets the applicable provisions of 14 CFR part 25, as amended by Amendments 25-1 through 25-137.

In addition, the certification basis includes certain special conditions,

exemptions, or later amended sections of the applicable part that are not relevant to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model GVII-G500 airplane because of a novel or unusual design feature, special conditions are prescribed under § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the Gulfstream Model GVII-G500 airplane must comply with the fuel-vent and exhaust-emission requirements of 14 CFR part 34, and the noise-certification requirements of 14 CFR part 36; and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92-574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, under § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Novel or Unusual Design Features

The Gulfstream Model GVII-G500 airplane incorporates the following novel or unusual design features: Electronic flight-control system providing control-surface awareness to the flightcrew.

Discussion

Gulfstream Aerospace Corporation is intending to utilize an electronic flight-control system (including side-stick controllers for pitch and roll control) in their new Model GVII-G500 airplane. With an electronic flight-control system and no direct coupling from the flightdeck controller to the control surface, the pilot may not be aware of the actual surface position utilized to fulfill the requested demand. Some unusual flight conditions, arising from atmospheric conditions, airplane malfunctions, or engine failures, may result in full or nearly full control-surface deflection. Unless the flightcrew is made aware of excessive deflection or impending control-surface limiting, piloted or auto-flight system control of the airplane might be inadvertently continued in such a manner as to cause loss of airplane control, or other unsafe stability or performance characteristics.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions apply to Gulfstream Model GVII-G500 airplanes. Should Gulfstream apply later for a change to the type certificate to include another model incorporating the same or similar novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on Gulfstream Model GVII-G500 airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Gulfstream Model GVII-G500 airplanes.

In addition to the requirements of §§ 25.143, 25.671, 25.672, and 25.1322, when a flight condition exists where, without being commanded by the crew, control surfaces are coming so close to their limits that return to the normal flight envelope, or continuation of safe flight, or both, requires a specific crew action, a suitable flight-control-position annunciation must be provided to the crew, unless other existing indications are found adequate or sufficient to prompt that action.

Note: The term “suitable” indicates an appropriate balance between necessary operation and nuisance factors.

Issued in Renton, Washington, on August 7, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015-20296 Filed 8-17-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA-2015-N-2723]

Medical Devices; Cardiovascular Devices; Classification of the Esophageal Thermal Regulation Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the esophageal thermal regulation device into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the esophageal thermal regulation device's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective August 18, 2015. The classification was applicable on June 23, 2015.

FOR FURTHER INFORMATION CONTACT: Lydia Glaw, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1102, Silver Spring, MD 20993-0002, 301-796-1456, Lydia.glaw@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or 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. The Agency 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) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On May 8, 2014, Advanced Cooling Therapy, LLC, submitted a request for classification of the Esophageal Cooling Device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies 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 to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device could be classified into class II with the