worldwide fleet. We estimate that 42 airplanes of U.S. registry will be affected by this AD, that it will take approximately 14 work hours per airplane to accomplish the required replacement and inspections, and that the average labor rate is $65 per work hour. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $38,220, or $910 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); 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. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by adding the following new airworthiness directive:

2004–20–02 Boeing: Amendment 39–13807. Docket 2003–NM–44–AD.

Applicability: All Model 707 and 720 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent stress corrosion cracking of the bolts and wearing of the joint between the lock support fitting and the support link, which could lead to failure of the joint and could cause the collapse of the main landing gear (MLG), accomplish the following:

Service Bulletin References

(a) The term ''service bulletin,'' as used in this AD, means the Accomplishment Instructions of Boeing 707 Alert Service Bulletin A3511, dated January 23, 2003.

Initial Inspection

(b) Within 12 months or 1,000 flight cycles after the effective date of this AD, whichever comes first, perform a high frequency eddy current (HFEC) inspection of the MLG lock support fitting and the support link for cracks and corrosion in accordance with the service bulletin.

Corrective Actions

(c) If any crack or corrosion is found, during the HFEC inspection required by paragraph (b) of this AD, before further flight, rework the lock support fitting or support link, in accordance with the service bulletin, except as specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) If the service bulletin specifies to contact Boeing for rework limits: Before further flight, repair or replace the lock support fitting or support link per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair/replacement method to be approved, the approval must specifically reference this AD.

(2) Where the service bulletin specifies to rework the forward and aft lug bore and faces common to the lock support fitting of the MLG as given in Boeing Service Bulletin 707–2837, this AD requires rework to be accomplished only in accordance with Revision 5 of Boeing 707 Service Bulletin 2837, dated March 31, 1978.

Replacement of Bolts and Bushings

(d) Within 12 months or 1,000 flight cycles after the effective date of this AD, whichever comes first, replace the bolts and bushings at the joint between the lock support fitting for the MLG and the wing fillet flap with new CRES bolts and Cadmium-plated Al-Ni-Br bushings in accordance with the service bulletin.

Parts Installation

(e) As of the effective date of this AD, only bolts specified in paragraph (e)(1) of this AD and bushings specified in paragraph (e)(2) of this AD, may be installed at the joint between the MLG lock support fitting and the support link, on any airplane.

(1) CRES bolts, part number (P/N) BACB30LR10DK56 or P/N BACB30LR10DK62.

(2) Cadmium-plated aluminum nickel bronze bushings as specified in the service bulletin.

Alternative Methods of Compliance

(f) In accordance with 14 CFR 39.19, the Manager, Seattle ACO, FAA, is authorized to approve alternative methods of compliance for this AD.

Incorporation by Reference

(g) Unless otherwise specified in this AD, the actions shall be done in accordance with Boeing 707 Alert Service Bulletin A3511, dated January 23, 2003. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Effective Date

(h) This amendment becomes effective on November 4, 2004.

Issued in Renton, Washington, on September 16, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–21649 Filed 9–29–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NE–57–AD; Amendment 39–13798; AD 2004–19–04]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc RB211–22B, RB211–524, and RB211–535 Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2004–19–04. That AD applies to Rolls-Royce plc (RR) RB211–22B, RB211–524, and RB211–535 series turbofan engines. That AD was published in the **Federal Register** on September 22, 2004 (69 FR 56683). In the amendatory language, under § 39.13 [Amended], the amendment number for the AD was inadvertently omitted. This document corrects that omission. In all other respects, the original document remains the same.

EFFECTIVE DATE: Effective September 30, 2004.

FOR FURTHER INFORMATION CONTACT: Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7175, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A final rule AD, FR Doc. 04–21173 that applies to RR RB211–22B, RB211–524, and RB211–535 series turbofan engines, was published in the **Federal Register** on September 22, 2004 (69 FR 56683). The following correction is needed:

§ 39.13 [Corrected]

■ On page 56684, in the second column, under § 39.13 [Amended], in the fifth line, ''2004–19–04 Rolls-Royce plc: Docket No.'' is corrected to read ''2004–19–04 Rolls-Royce plc: Amendment 39–13798. Docket No.''.

Issued in Burlington, MA, on September 23, 2004.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 04–21912 Filed 9–29–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. 2004P–0354]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of Sirolimus Test System Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the sirolimus test system device into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: Sirolimus Test Systems.'' The device is intended to measure sirolimus levels in whole blood as an aid to managing therapy for transplant patients receiving sirolimus, an immunosuppressive drug. 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. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a guidance document that is the special control for this device.

DATES: This rule becomes effective November 1, 2004. The classification was effective July 28, 2004.

FOR FURTHER INFORMATION CONTACT: Avis Danishefsky, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, ext. 161.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the 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 (the amendments), 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 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 act, to a predicate device. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a document in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued a document on June 15, 2004, classifying the Microgenics CEDIA Sirolimus Assay in class III because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On June 16, 2004, Microgenics Corp. submitted a petition requesting classification of the Microgenics CEDIA Sirolimus Assay under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified 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 petition, FDA determined that the Microgenics CEDIA Sirolimus Assay can be classified in class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name sirolimus test system and is identified as a device intended to quantitatively determine sirolimus concentrations in whole blood. Measurements are used as an aid in management of transplant patients receiving therapy with sirolimus.

FDA has identified no direct risks to health related to use of sirolimus test systems. However, FDA has identified improper patient management, which involves failure of the test to perform as indicated or error in interpretation of results, as an indirect risk to health related to use of this device. For example, a falsely low sirolimus measurement could contribute to a decision to raise the sirolimus dose above that which is necessary for therapeutic benefit. This could result in increased risk in the form of thrombocytopenia, leukopenia, anemia, or hyperlipidemia. A falsely high sirolimus measurement could contribute to a decision to decrease the dose below