paragraph (e) of this section, and ten days before the scheduled date of the deposition, the deponent shall submit an electronic index of all documents in his or her possession, relevant to the subject matter of the deposition, including the categories of documents set forth in paragraph (i)(2) of this section, to all parties and interested governmental participants. The index shall identify those records which have already been made available electronically. All documents that are not identical to documents already made available electronically, whether by reason of subsequent modification or by the addition of notations, shall be treated as separate documents.

(2) The following material is excluded from the initial requirements of § 2.1003 to be made available electronically, but is subject to derivative discovery under paragraph (i)(1) of this section—

(i) Personal records;

(ii) Travel vouchers;

(iii) Speeches;

(iv) Preliminary drafts;

(v) Marginalia.

(3) Subject to paragraph (i)(6) of this section, any party or interested governmental participant may request from the deponent a paper copy of any or all of the documents on the index that have not already been provided electronically.

(4) Subject to paragraph (i)(6) of this section, the deponent shall bring a paper copy of all documents on the index that the deposing party or interested governmental participant requests that have not already been provided electronically to an oral deposition conducted pursuant to paragraph (a) of this section, or in the case of a deposition taken on written questions pursuant to paragraph (e) of this section, shall submit such documents with the certified deposition.

(5) Subject to paragraph (i)(6) of this section, a party or interested governmental participant may request that any or all documents on the index that have not already been provided electronically, and on which it intends to rely at hearing, be made electronically available by the deponent.

(6) The deposing party or interested governmental participant shall assume the responsibility for the obligations set forth in paragraphs (i)(1), (i)(3), (i)(4), and (i)(5) of this section when deposing someone other than a party or interested governmental participant.

* * * * *

Dated at Rockville, Maryland, this 22nd day of December, 1998.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 98–34436 Filed 12–29–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–SW–40–AD; Amendment 39–10969; AD 99–01–02]

RIN 2120–AA64

Airworthiness Directives; Westland Helicopters Ltd. 30 Series 100 and 100–60 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to Westland Helicopters Ltd. (Westland) 30 Series 100 and 100–60 helicopters. This action requires the removal and replacement of conformal pinion quill shafts installed in certain main rotor gearboxes that fail to pass a magnetic drain plug inspection. This amendment is prompted by a report of a forced landing that occurred when a single conformal pinion quill shaft failed in a main rotor gearbox (MRGB). This condition, if not corrected, could result in the failure of a MRGB, and a subsequent forced landing or loss of control of the helicopter.

DATES: Effective January 14, 1999.

Comments for inclusion in the Rules Docket must be received on or before March 1, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 97-SW–40, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

The service information referenced in this AD may be obtained from Westland Helicopters Ltd., Customer Support Division, Yeovil, Somerset BA20 2YB, England, telephone (01935) 703884, fax (01935) 703905. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Shep Blackman, Aerospace Engineer, FAA, Rotorcraft Directorate, Fort Worth, Texas 76193–0111, telephone (817) 222–5296, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom (UK), notified the FAA that an unsafe condition may exist on Westland 30 series helicopters. The UK CAA advised that an incident of a conformal pinion quill shaft failure within an MRGB occurred, resulting in a forced landing. Further investigation revealed that this MRGB had a history of shock loading, defined as a slam engagement of the No. 1 engine free wheeling unit that can occur when the No. 1 engine condition lever is at ''GND'' or ''FLT'' position and the engine is driving accessories but the main rotor is not turning. If the No. 1 engine free wheel is slam engaged, the No. 1 engine power turbine will abruptly stop, causing potential damage to the MRGB and other drive system components. Westland has issued Westland Helicopters Ltd. Service Bulletin W30–63–75, dated November 29, 1995 (SB), that requires the removal and replacement of the conformal pinion quill shafts within a MRGB identified by serial number or with a history of shock loading. The UK CAA classified this SB as mandatory and issued UK CAA AD 012–11–95, dated January 31, 1996, to ensure the continued airworthiness of these helicopters in the UK.

These helicopter models are manufactured in Yeovil, England, and are type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the UK CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the UK CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

This AD is being issued to prevent a forced landing or possible loss of control of the helicopter due to failure of the conformal pinion quill shafts installed in the MRGB in certain Westland 30 series helicopters. This AD requires, prior to further flight, a magnetic drain plug inspection of an installed MRGB with a serial number listed in this AD or with a history of shock loading. If the magnetic drain plug passes inspection, the MRGB may

remain in service a maximum of 100 additional hours time-in-service (TIS) after the effective date of this AD. If the magnetic drain plug fails inspection, the MRGB must be removed from service prior to further flight and the conformal pinion quill shaft has to be replaced with an airworthy conformal pinion shaft in accordance with the Westland Maintenance Manual.

None of the Westland 30 series helicopters affected by this action are on the U.S. Register. All helicopters included in the applicability of this rule are currently operated by non-U.S. operators under foreign registry; therefore, they are not directly affected by this AD action. However, the FAA considers this rule necessary to ensure that the unsafe condition is addressed in the event that any of these subject helicopters are imported and placed on the U.S. Register in the future.

Should an affected helicopter be imported and placed on the U.S. Register in the future, it would require approximately 1.5 work hours to inspect the magnetic drain plug and 20 work hours to replace, if necessary, the MRGB. The average labor rate is $60 per work hour. A replacement MRGB, if needed, costs $350,000. Based on these figures, the cost impact of this AD would be $350,090 per helicopter; $90 for the inspection and $350,000 for the replacement, if necessary, of the MRGB.

Since this AD action does not affect any helicopter that is currently on the U.S. Register, it has no adverse economic impact and imposes no additional burden on any person. Therefore, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–SW–40–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that notice and prior public comment are unnecessary in promulgating this regulation and therefore, it can be issued immediately to correct an unsafe condition in aircraft since none of these model helicopters are registered in the United States, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, 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, 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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

AD 99–01–02 Westland Helicopters Ltd (Westland): Amendment 39–10969. Docket No. 97–SW–40–AD.

Applicability: Westland 30 Series 100 and 100–60 Helicopters, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (c) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any rotorcraft from the applicability of this AD.

Compliance: Required as indicated unless accomplished previously.

To prevent failure of the conformal pinion quill shafts installed in certain Westland 30 series helicopters main rotor gearboxes that could result in a subsequent forced landing or loss of control of the helicopter, accomplish the following:

(a) Prior to further flight, determine if the installed main rotor gearbox (MRGB) has a serial number included in the following list or has a history of shock loading. Shock loading is defined as a slam engagement of the No. 1 engine free wheeling unit that can occur when the No. 1 engine condition lever is at ''GND'' or ''FLT'' position and the engine is driving accessories but the main rotor is not turning. If the No. 1 engine freewheel is then engaged, the No. 1 engine power turbine will abruptly stop, causing potential damage to the MRGB and other drive system components.

AAT 4440	ABL 5602	ACD 2875
AAX 4726	ABN 8930	ACN 7996
ABC 9438	ABP 3947	ADE 6100
ABD 7294	ABP 9028	WAG 397
ABG 5056	ABT 3965	WAG 410
ABH 5075	ABW 0547	WAK 525
ABJ 9595	ACA 3707	WAK 561
ABK 9484	.....	

(b) If the installed MRGB has a serial number listed in paragraph (a) of this AD or has a history of shock loading, perform a magnetic drain plug inspection.

(1) If the magnetic drain plug passes inspection, the MRGB may remain in service a maximum of 100 additional hours time in service (TIS) after the effective date of this AD with a repetitive magnetic drain plug inspection at intervals not to exceed 25 hours TIS. The MRGB must then be removed from service and the conformal pinion quill shafts replaced.

(2) If the magnetic drain plug fails inspection, remove the MRGB from service prior to further flight and replace the conformal pinion quill shafts.

Note 2: Westland Helicopters, Ltd. Service Bulletin No. W30–63–75, dated November 29, 1995 (SB) pertains to the subject of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Rotorcraft Standards Staff, Rotorcraft Directorate. Operators shall submit their requests through an FAA Principal Maintenance Inspector who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff, Rotorcraft Directorate.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(f) This amendment becomes effective on January 14, 1999.

Note 4: The subject of this AD is addressed in Civil Aviation Authority (United Kingdom) AD 012–11–95.

Issued in Fort Worth, Texas, on December 21, 1998.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 98–34502 Filed 12–29–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 97N–0239]

Dental Devices; Effective Date of Requirement for Premarket Approval; Temporomandibular Joint Prostheses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for certain devices, namely, the total temporomandibular joint (TMJ) prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis (for permanent reconstruction), and the interarticular disc prosthesis. At a later date, FDA will propose reclassifying from class III into class II the generic type of temporary mandibular condyle prosthesis intended for temporary reconstruction following surgical ablation of malignant and benign tumors. This action establishing the effective date of the premarket approval requirement for certain devices is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the FDA Modernization Act of 1997 (FDAMA).

DATES: This regulation is effective December 30, 1998.

FOR FURTHER INFORMATION CONTACT: Mary S. Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory History of the Devices

In the **Federal Register** of December 20, 1994 (59 FR 65475), FDA issued a final rule classifying the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis, and the interarticular disc prosthesis (interpositional implant) into class III. The preamble to the proposal (57 FR 43165, September 18, 1992) to classify these devices included the recommendation of the Dental Products Panel of the Medical Devices Advisory Committee (the Panel), an FDA advisory committee, which met on April 21, 1989, regarding the classification of the devices, in particular, the total TMJ prosthesis and the interarticular disc prosthesis (interpositional implant). The preamble to the reproposed rule (59 FR 6935, February 14, 1994) to classify the glenoid fossa prosthesis and the mandibular condyle prosthesis included the recommendation of the Panel that reconvened on February 11, 1993, regarding the classification of these two devices. The Panel recommended, at the April 1989 meeting, that the total TMJ prosthesis and the interarticular disc prosthesis (interpositional implant) be classified into class III, and at the February 1993 meeting, the Panel recommended that the glenoid fossa prosthesis and the mandibular condyle prosthesis also be classified into class III, and identified certain risks to health presented by the devices. The Panel believed that the devices presented a potential unreasonable risk to health and that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish performance standards which would provide reasonable assurance of the safety and effectiveness of the devices. FDA agreed with the Panel's recommendations and, in the September 18, 1992, proposal (57 FR 43165), and the February 14, 1994, reproposal (59 FR 6935), proposed that the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis and the interarticular disc prosthesis (interpositional implant) be classified into class III. The proposal and reproposal stated that FDA believed that general controls, either alone or in combination with the special controls applicable to class II devices are insufficient to provide reasonable assurance of the safety and effectiveness of the devices. The proposal and reproposal stated that premarket approval is necessary for the devices because the devices present potential unreasonable risks of illness or injury if there are not adequate data to ensure the safe and effective use of the devices. The preamble to the December 20, 1994, final rule (59 FR 65475) classifying the total TMJ prosthesis, the glenoid fossa prosthesis, the mandibular condyle prosthesis and the interarticular disc prosthesis (interpositional implant) into class III advised that the earliest date by which PMA's or notices of completion of PDP's for the devices could be required was June 30, 1997, or 90 days after issuance of a rule requiring premarket approval for the devices.

In the **Federal Register** of January 6, 1989 (54 FR 550), FDA issued a notice of intent to initiate proceedings to require premarket approval for 31 class III preamendments devices. Among other items, the notice described the factors FDA takes into account in establishing priorities for proceedings under section 515(b) of the act (21 U.S.C. 360e(b)) for issuing final rules requiring that preamendments class III devices have approved PMA's or declared completed PDP's. FDA updated its priorities in a preamendments class III strategy document made public through a **Federal Register** notice of availability published on May 6, 1994 (59 FR 23731). Though the above TMJ