(3) For each S–G with more than 110 hours TIS since initial installation, measure the vibration level before further flight.

(c) After doing paragraph (b) of this AD, thereafter, at intervals not to exceed 110 hours TIS, measure the vibration level in accordance with paragraph 2.A.2. of the Telex.

(d) If the vibration level of an S–G is equal to or greater than 0.5 inches per second (IPS) (12.7 mm/s):

(1) Remove the S–G and repair or replace it with an airworthy S–G.

(2) Visually inspect the four ejector attachment lugs (lugs) and the two clamps for a crack in accordance with the Accomplishment Instructions, paragraph 2.B.3.b.1B), of the Telex.

(3) Inspect the two half-clamps for a crack.

(4) Remove the S–G to engine attachment flange (flange). Clean and inspect the flange for a crack in accordance with the Accomplishment Instructions, paragraph 2.B.3.b.1D) of the Telex.

(5) If a crack is found, before further flight, repair or replace the cracked part with an airworthy part in accordance with the Accomplishment Instructions, paragraph 2.B.3.b.3 of the Telex, except you are not required to report your findings to the manufacturer.

(e) 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, Regulations Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

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

(g) Measuring the vibration level, inspecting the lugs or clamps, and replacing the parts shall be done in accordance with the Accomplishment Instructions, Eurocopter France Telex No. 01.00.45 Revision 3, dated November 22, 2001. 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 American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected 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.

(h) This amendment becomes effective on December 17, 2002.

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD Nos. 1999–469–058(A) Revision 1, dated August 9, 2000, and 1999–469–058(A) Revision 2, dated January 9, 2002.

Issued in Fort Worth, Texas, on October 29, 2002.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 02–28412 Filed 11–8–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–CE–23–AD; Amendment 39–12944; AD 2002–22–17]

RIN 2120–AA64

Airworthiness Directives; Cessna Aircraft Company Models 208 and 208B Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that applies to all Cessna Aircraft Company (Cessna) Models 208 and 208B airplanes. This AD requires you to repetitively inspect the inboard forward flap bellcranks for cracks or replace bellcranks depending on the amount of usage. This AD is the result of Cessna re-evaluating the bellcrank life limit analysis and determining that the original estimate is too high. The actions specified by this AD are intended to detect, correct, and prevent future cracks in the bellcrank, which could result in failure of this part. Such failure could lead to damage to the flap system and surrounding structure and result in reduced or loss of control of the airplane.

DATES: This AD becomes effective on December 31, 2002.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulations as of December 31, 2002.

ADDRESSES: You may get the service information referenced in this AD from Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; telephone: (316) 517–5800; facsimile: (316) 942–9006. You may view this information at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2002–CE–23-AD, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Paul Nguyen, Aerospace Engineer, FAA, Aircraft Certification Office, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: 316–946–4125; facsimile: 816–946–4407.

SUPPLEMENTARY INFORMATION:

Discussion

What Events Have Caused This AD?

A search by the FAA of the service difficulty database has revealed 10 cracked bellcrank incidents on Cessna Models 208 and 208B airplanes. As a result, Cessna has re-evaluated the bellcrank life limit analysis and determined 7,000 landings is more accurate than the original estimate of 9,000 landings. Cessna has revised the Models 208 and 208B Maintenance Manual and developed a service bulletin to notify the public that the inboard forward flap bellcrank life limit has been reduced to 7,000 landings. Since some Model 208 airplanes have exceeded 7,000 landings, we have determined that an AD is necessary to require replacement of the bellcrank in those airplanes.

What Is the Potential Impact if FAA Took No Action?

If not detected and corrected, a cracked bellcrank could fail. Such failure could lead to damage to the flap system and surrounding structure and result in reduced or loss of control of the airplane.

Has FAA Taken Any Action to This Point?

We issued a proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an AD that would apply to all Cessna Models 208 and 208B airplanes. This proposal was published in the **Federal Register** as a notice of proposed rulemaking (NPRM) on June 26, 2002 (67 FR 43056). The NPRM proposed to repetitively inspect the inboard forward flap bellcranks for cracks or replace bellcranks depending on the amount of usage and reduce the life limits of the bellcranks from 9,000 landings to 7,000 landings.

Was the Public Invited to Comment?

The FAA encouraged interested persons to participate in the making of this amendment. The following presents the comments received on the proposal and FAA's response to each comment:

Comment Issue 1: Which Flap Bellcrank(s) Does the Proposed AD Affect?

What Is the Commenter's Concern?

A commenter asks if the proposed AD only affects the right inboard flap bellcrank or the right and the left flap inboard bellcranks?

What Is FAA's Response to the Concern?

The Cessna Model 208 airplane has only one inboard flap bellcrank assembly and it is located on the right hand side of the aircraft. This flap bellcrank assembly controls both the right and left flaps. Therefore, inspection of the only flap bellcrank assembly in accordance with the Cessna Service Bulletin CABO2–1 will comply with the proposed AD.

We have not changed the final rule as a result of this comment.

Comment Issue 2: The Limits in the Service Information Are Sufficient and the Proposed AD Is Not Warranted.

What is the Commenter's Concern?

A commenter states that Cessna has revised their airworthiness limitations to reflect what the NPRM proposes. The limitations now include a 7,000 landings limit, with repetitive inspections every 500 landings until 7,000 landings are accumulated. For this reason, the commenter recommends that we withdraw the NPRM.

What is FAA's Response to the Concern?

We disagree. Airworthiness Directives that apply more restrictive limits to products are issued when the current limits contribute to an unsafe condition. The AD establishes a deadline to come into compliance with the new life limits.

We have not changed the final rule as a result of this comment.

FAA's Determination

What Is FAA's Final Determination on This Issue?

We carefully reviewed all available information related to the subject presented above and determined that air safety and the public interest require the adoption of the rule as proposed except for the changes discussed above and minor editorial questions. We have determined that these changes and minor corrections:

—Provide the intent that was proposed in the NPRM for correcting the unsafe condition; and

—Do not add any additional burden upon the public than was already proposed in the NPRM.

Cost Impact

How Many Airplanes Does This AD Impact?

We estimate that this AD affects 1,300 airplanes in the U.S. registry.

What Is the Cost Impact of This AD on Owners/Operators of the Affected Airplanes?

We estimate the following costs to accomplish the inspection:

Labor Cost	Parts Cost	Total Cost Per Airplane	Total Cost on U.S. Operators
1 workhour × $60 per hour = $60 ...	No cost for parts	$60	$60 × 1,300 = $78,000

We estimate the following costs to accomplish any necessary replacements that would be required based on the reduced life limits:

Labor Cost	Parts Cost	Total Cost Per Airplane	Total Cost on U.S. Operators
3 workhours × $60 per hour = $180	$1,793	$180 + $1,793 = $1,973	$1,973 × $1,300 = $2,564,900

Regulatory Impact

Does This AD Impact Various Entities?

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.

Does This AD Involve a Significant Rule or Regulatory Action?

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 copy of the final evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting 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, under 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. FAA amends § 39.13 by adding a new AD to read as follows:

2002–22–17 Cessna Aircraft Company: Amendment 39–12944; Docket No. 2002–CE–23–AD.

(a) *What airplanes are affected by this AD?* This AD affects Models 208 and 208B airplanes, all serial numbers, that are certificated in any category.

(b) *Who must comply with this AD?* Anyone who wishes to operate any of the airplanes identified in paragraph (a) of this AD must comply with this AD.

(c) *What problem does this AD address?* The actions specified by this AD are intended to detect, correct, and prevent cracks in the bellcrank, which could result in failure of this part. Such failure could lead to damage to the flap system and surrounding structure and result in reduced or loss of control of the airplane.

(d) *What actions must I accomplish to address this problem?* To address this problem, you must accomplish the following:

Actions	Compliance	Procedures
(1) Inspect, using eddy current inspection, the inboard forward flap bellcrank for cracks.	Initially inspect upon the accumulation of 4,000 landings on the bellcrank or within the next 250 landings after December 31, 2002 (the effective date of this AD), whichever occurs later. Repetitively inspect thereafter at every 500 landings until 7,000 landings are accumulated.	In accordance with the Inspection Instructions of Cessna Service Bulletin No. CAB02–1, dated February 11, 2002, and the applicable maintenance manual.
(2) Replace the inboard forward flap bellcrank.	Prior to further flight when cracks are found; and upon the accumulation of 7,000 landings or within the next 75 landings after December 31, 2002 (the effective date of this AD), whichever occurs later.	In accordance with the Inspection Instructions of Cessna Service Bulletin No. CAB02–1, dated February 11, 2002, and the applicable maintenance manual.

Note 1: Inboard forward flap bellcranks with 7,000 landings or more do not have to be replaced until 75 landings after the effective date of this AD.

Note 2: The compliance times of this AD are presented in landings instead of hours. If the number of landings is unknown, hours time-in-service (TIS) may be used by multiplying the number of hours TIS by 1.25.

(e) *Can I comply with this AD in any other way?* You may use an alternative method of compliance or adjust the compliance time if:

(1) Your alternative method of compliance provides an equivalent level of safety; and

(2) The Manager, Wichita Aircraft Certification Office (ACO), approves your alternative. Submit your request through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 3: This AD applies to each airplane identified in paragraph (a) of this AD, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if you have not eliminated the unsafe condition, specific actions you propose to address it.

(f) *Where can I get information about any already-approved alternative methods of compliance?* Contact Paul Nguyen, Aerospace Engineer, FAA, Aircraft Certification Office, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: 316–946–4125; facsimile: 816–946–4407.

(g) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

(h) *Are any service bulletins incorporated into this AD by reference?* Actions required by this AD must be done in accordance with Cessna Service Bulletin No. CAB02–1, dated February 11, 2002. The Director of the Federal Register approved this incorporation by reference under 5 U.S.C. 552(a) and 1 CFR part 51. You may get copies from Cessna Aircraft Company, Product Support, PO Box 7706, Wichita, Kansas 67277; telephone: (316) 517–5800; facsimile: (316) 942–9006. You may view copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri, or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(i) *When does this amendment become effective?* This amendment becomes effective on December 31, 2002.

Issued in Kansas City, Missouri, on October 31, 2002.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–28408 Filed 11–8–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02N–0010]

Dental Devices; Classification for Intraoral Devices for Snoring and/or Obstructive Sleep Apnea

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the intraoral devices for snoring and/or obstructive sleep apnea into class II (special controls). These devices are used to control or treat simple snoring and/or obstructive sleep apnea. This classification is based on the recommendations of the Dental Devices Panel (the Panel), and is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. This action 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 Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the guidance document that will serve as the special control for this final rule.

DATES: This rule is effective December 12, 2002.

FOR FURTHER INFORMATION CONTACT: Susan 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

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and the FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), are generally referred to as preamendments devices, and are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.