Replacement of Hydraulic Hoses

(a) Replace the hydraulic hoses leading to the actuators of the flaps, main landing gear (MLG), nose landing gear (NLG), NLG downlock, and NLG wheel well, with new hydraulic hoses by doing all of the actions per the Accomplishment Instructions of Saab Service Bulletin 340–29–022, Revision 01, dated February 20, 2003. Do the replacement at the times specified in paragraphs (a)(1) and (a)(2) of this AD, as applicable.

(1) For airplanes on which affected hydraulic hoses have accumulated 12,000 or more total flight cycles since new: Within the next 5,000 flight cycles or 24 months after the effective date of this AD, whichever is first.

(2) For airplanes on which affected hydraulic hoses have accumulated less than 12,000 total flight cycles since new: Before the accumulation of 12,000 total flight cycles or within 24 months after the effective date of this AD, whichever is later.

Alternative Methods of Compliance

(b) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, is authorized to approve alternative methods of compliance for this AD.

Note 1: The subject of this AD is addressed in Swedish airworthiness directive 1–170, dated December 17, 2001.

Issued in Renton, Washington, on February 24, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–4940 Filed 3–4–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket FAA 2003–16567; Airspace Docket 03–ANM–14]

Proposed Revision of Class E Airspace; Sunriver, OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposal would revise Class E airspace at Sunriver Airport, Sunriver, OR. The establishment of a new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) requires additional Class E airspace extending upward from 700 feet or more above the surface of the earth north of the Sunriver Airport. This additional Class E airspace is necessary for the safety of Instrument Flight Rules (IFR) aircraft executing the new RNAV GPS SIAPs at Sunriver Airport.

DATES: Comments must be received by April 19, 2004.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number, FAA–2003–16567 Airspace Docket No. 03–ANM–14, at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov.* You may review the public docket containing the proposal, any comments received, and any final dispositions in person in the Docket Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone number 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the Office of the Regional Air Traffic Division, Northwest Mountain Region, Federal Aviation Administration, Airspace Branch, ANM–520, 1601 Lind Avenue, SW., Renton, WA 98055.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify Docket FAA–2003–16567; Airspace Docket 03–ANM–14, and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit, with those comments, a self-addressed stamped postcard on which the following statement is made: ''Comments to Docket FAA–2003–16567; Airspace Docket 03–ANM–14.'' The postcard will be date/time stamped and returned to the commenter.

Availability of NPRM

An electronic copy of this document may be downloaded through the Internet at *http://dms.dot.gov.* Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov* or the Superintendent of Document's Web page at *http://www.access.gpo.gov/nara.*

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, WA, 98055. Communications must identify both document numbers for this notice. Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, at 202–267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedures.

The Proposal

This action proposes to amend title 14 Code of Federal Regulations, part 71 (14 CFR part 71) by revising Class E airspace at Sunriver Airport, Sunriver, OR. The establishment of a new RNAV GPS SIAPs requires additional Class E controlled airspace extending upward from 700 feet or more above the surface of the earth north of the Sunriver Airport. This additional Class E airspace is necessary for the safety of IFR aircraft executing the new RNAV GPS SIAPs at Sunriver Airport. Controlled airspace is developed where there is a requirement for IFR services, which includes arrival, departures, and transitioning to/from the terminal or en route environment.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9L dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, is amended as follows.

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM OR E5 Sunriver, OR (Revised)

Sunriver Airport, Sunriver, OR
(Lat. 43°52′35″N., long. 121°27′11″W.)
Deschutes VORTAC
(Lat. 43°51′10″N., long. 121°18′13″W.)

That airspace extending upward from 700 feet above the surface of the earth within a 6.1 mile radius of the Sunriver Airport and within 3.5 miles each side of the Deschutes VORTAC 196° radial extending from the 6.1 mile radius to 14 miles north of the airport.

* * * * *

Issued in Seattle, Washington, on February 18, 2004.

Raul C. Treviño,

Acting Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 04–5033 Filed 3–4–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 2003N–0561]

Orthopedic Devices; Effective Date of the Proposed Requirement for Premarket Approval of the Hip Joint Metal/Polymer or Ceramic/Polymer Semiconstrained Resurfacing Cemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the hip joint metal/polymer or ceramic/polymer semiconstrained resurfacing cemented prosthesis. The agency is summarizing its proposed findings regarding the degree of risk of illness or injury intended to be eliminated or reduced by requiring the device to meet the statute's approval requirements as well as the benefits to the public from the use of the device. The agency also is proposing to revise the name and identification of the device. In addition, FDA is announcing the opportunity for interested persons to request the agency to change the classification of the device based on new information. FDA is taking this action 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), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: Submit written or electronic comments by June 3, 2004; submit written or electronic requests for a change in classification by March 22, 2004.

ADDRESSES: Submit written comments or requests for a change in classification to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Pei Sung, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the act (21 U.S.C. 360(c)) requires FDA to classify medical devices into one of three regulatory categories (classes): Class I (general controls), class II (special controls), and class III (premarket approval). Generally, FDA has classified, or is classifying, devices that were on the market before May 28, 1976, the date of enactment of the 1976 amendments, and devices marketed on or after that date that are substantially equivalent to such devices. For convenience, this preamble refers to the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. An applicant may commercially distribute a preamendments class III device without an approved PMA or a notice of completion of a PDP until 90 days after the effective date that FDA issues in a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, an applicant may commercially distribute a preamendments device subject to the rulemaking procedure under section 515(b) without an approved investigational device exemption (IDE) part 812 (21 CFR part 812) until the date FDA identifies in the final rule requiring the submission of a PMA or PDP for the device. At that time, an applicant must submit an IDE if a PMA has not been submitted or a PDP has not been declared completed.

Section 515(b)(2)(A) of the act provides a proceeding to issue a final rule to require premarket approval. The agency must initiate the process by publishing a notice of proposed rulemaking in the **Federal Register**. The notice must contain: (1) The proposed rule, (2) the proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity to submit comments on the proposed rule and the proposed findings, and (4) an opportunity to request reclassification of the device based on relevant new information.

If FDA receives a request to reclassify the device within 15 days of publication of the notice, section 515(b)(2)(B) of the act requires the agency to take the following action. Within 60 days of the publication of the notice, FDA must consult with the appropriate FDA advisory committee and publish a notice denying the requested reclassification or announcing the agency's intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act requires FDA, after the close of the comment period on the proposed