**§ 39.13 [Amended]**

2. The FAA amends § 39.13 by adding the following new airworthiness directive:

**Eurocopter France:** Docket No. 2001–SW–03–AD.

*Applicability:* Model AS–365N3 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 otherwise 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 request approval for an alternative method of compliance in accordance with paragraph (b) 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 the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Within 90 days after the effective date of this AD, unless previously accomplished.

To prevent loss of the Full Authority Digital Engine Control (FADEC) one-engine-inoperative power and subsequent loss of control of the helicopter, accomplish the following:

(a) Modify the FADEC software in accordance with the Accomplishment Instructions of Eurocopter France Service Bulletin 71.00.13, Revision 1, dated October 17, 2000 (except this AD does not require contact with the manufacturer as specified in the caution statement in paragraph 2.B. and the Note I in paragraph 2.B.2.).

(b) 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.

(c) 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.

**Note 3:** The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD Nos. 2000–517–051(A) and 1998–517–048(A) R2, both dated December 13, 2000; 1998–517–048(A) R1, dated April 5, 2000; and 1998–517–048(A), dated January 13, 1999.

Issued in Fort Worth, Texas, on April 26, 2001.

**Mark R. Schilling,**

*Acting Manager, Rotorcraft Directorate,, Aircraft Certification Service.*

[FR Doc. 01–11585 Filed 5–8–01; 8:45 am]

BILLING CODE 4910–13–U

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 864

**[Docket No. 95P–0351]**

## Hematology and Pathology Devices; Reclassification of Automated Differential Cell Counters

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to reclassify from class III (premarket approval) to class II (special controls) the automated differential cell counter (ADCC). The ADCC is a device intended to identify and classify one or more of the formed elements of the blood, or to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. FDA is basing this reclassification on new information submitted in a reclassification petition from the International Society for Laboratory Hematology (ISLH). The agency 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), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**DATES:** Submit written comments by August 7, 2001.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Larry J. Brindza, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

**SUPPLEMENTARY INFORMATION:**

### I. Background (Regulatory Authorities)

The act, as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and 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), generally referred to as preamendments devices, 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.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not

available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); and *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, ''new information'' to support reclassification under section 513(e) of the act must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).) FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., nonpublic information in a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

## II. Regulatory History of the Device

In the **Federal Register** of June 8, 1990 (55 FR 23510), FDA issued a final rule that amended 21 CFR 864.5220 to reclassify the ADCC intended to flag or identify specimens containing abnormal blood cells from class III into class II. The rule continued to classify the ADCC intended for all other uses into class III. FDA based the rule on new information in a petition from the Health Industry Manufacturers Association.

On September 22, 1995, Abbott Laboratories, Santa Clara, CA 95054, submitted a petition under sections 513(e) and 515(b) of the act to reclassify the ADCC from class III to class II for its general uses in identifying and counting blood elements and cells. On September 4, 1997, FDA received a letter from ISLH announcing that ISLH was replacing Abbott Laboratories as the petitioner. Consistent with the act and the regulations, FDA referred the petition to the Hematology and Pathology Device Panel (the Panel) for its recommendation on the change in classification requested by the petitioner. The Panel based its recommendation to reclassify the ADCC from class III to class II on the belief that special controls, including voluntary standards and guidance documents, as well as published references, and the clinical experience of the Panel, are sufficient to provide reasonable assurance of the safety and effectiveness of the ADCC. Accordingly, FDA is now proposing to reclassify the ADCC from class III (premarket approval) to class II (special controls) when the device is intended to be used to identify and classify one or more of the formed elements of the blood, or to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids.

## III. Proposed Dates

FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

## IV. Device Description

An ADCC is a device used to identify one or more of the formed elements of the blood. These devices may also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device may include accessory CD markers.

## V. Recommendation of the Panel

On January 20, 1999, the Panel recommended that the ADCC be reclassified from class III to class II. The Panel believed that classification in class II with the special control ''Guidance for Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells'' would provide reasonable assurance of the safety and effectiveness of the device.

## VI. Risks to Health

Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a blood cell disorder. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

## VII. Summary of Reasons for Recommendation

The Panel believes that the ADCC should be reclassified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance. Adherence to ''Guidance for Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells'' can control the risk of misdiagnosis and inappropriate therapy by having the manufacturer provide appropriate data to support all claims for substantial equivalence and performance of ADCC.

## VIII. Summary of Data Upon Which the Recommendation Is Based

The performance characteristics of the technology used in ADCCs over many years of experience plus the proven safety and effectiveness of the device are well documented in the medical literature (Ref. 1). FDA can evaluate performance characteristics for abnormal cell types such as nucleated red blood cells and immature reticulocyte fraction in 510(k) submissions (Refs. 2, 3, and 4). Based on the available information, FDA believes that the special control discussed below is capable of providing reasonable assurance of the safety and effectiveness of the automated differential cell counter for the identified risks to health of this device.

## IX. Special Controls

In addition to general controls, FDA believes that the ''Guidance for Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells'' is an adequate special control to address the risks to health described above.

In order to receive ''Guidance for Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At second voice prompt press 1 to order a document. Enter the document number (1184) followed by the pound sign (#). Follow the remaining voice prompts to complete your request. Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Guidance for Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved

applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

**X. FDA's Tentative Findings**

FDA agrees with the recommendation of the Panel and believes ADCCs should be classified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

**XI. Environmental Impact**

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**XII. Analysis of Impacts**

FDA has examined the impacts of this proposed rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this reclassification action is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the reclassification action is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

**XIII. Paperwork Reduction Act of 1995**

The proposed rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C 3501–3520).

**XIV. Request for Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposal by August 7, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**XV. References**

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 am. and 4 p.m., Monday through Friday:

1. Various authors, ''The White Blood Cell Differential,'' Parts I & II, *Blood Cells* 11:1–314, 1985.

2. Dutcher, T. F., ''Leukocyte Differentials, Are They Worth The Effort?'' *Clinics in Laboratory Medicine* 4 (1): 71–87, 1984.

3. Rumke, C. L., ''The Statistically Expected Variability in Differential Leukocyte Counting,'' In: *Differential Leukocyte Counting*,'' edited by J. A. Koepke, College of American Pathologists, Skokie, IL, pp. 39–45, 1977.

4. Rumke, C. L., ''Statistical Reflections in Finding Atypical Cells,'' *Blood Cells* 11: 141–144, 1985.

**List of Subjects in 21 CFR Part 864**

Biologics, Blood, Laboratories, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes that 21 CFR part 864 be amended as follows:

## PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 864.5220 is revised to read as follows:

**§ 864.5220 Automated differential cell counter.**

(a) *Identification.* An automated differential cell counter is a device used to identify one or more of the formed elements of the blood. The device may also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device includes accessory CD markers.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Guidance for Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells.''

Dated: April 28, 2001.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 01–11580 Filed 5–8–01; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF TRANSPORTATION

## Federal Highway Administration

## 23 CFR Part 710

**[FHWA Docket No. FHWA 2001–8624]**

**RIN 2125–AE82**

## Right-of-Way and Real Estate; Program Administration

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM); request for comments.

**SUMMARY:** The FHWA is proposing to amend its right-of-way regulations for federally assisted transportation projects to provide a clarification. The proposed amendment would make it clear that