DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. 95P–0315]

Hematology and Pathology Devices; Reclassification of the Automated Differential Cell Counter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the automated differential cell counter (ADCC) from class III (premarket approval) into class II (special controls). FDA is also identifying the guidance document entitled ''Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA'' as the special control that the agency believes will reasonably ensure the safety and effectiveness of the device. This reclassification is being undertaken based on new information submitted in a reclassification petition from the International Society for Laboratory Hematology (ISLH), under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 and the FDA Modernization Act of 1997.

DATES: This rule is effective February 13, 2002.

ADDRESSES: Comments and the guidance may be seen at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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

In the **Federal Register** of May 9, 2001 (66 FR 23634), FDA published a proposed rule to reclassify the automated differential cell counter from class III (premarket approval) into class II (special controls) based on new information regarding this device and on the recommendation of the Hematology and Pathology Devices Panel. FDA also identified the document ''Guidance for Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells'' as the special control capable of providing reasonable assurance of safety and effectiveness for this device. The agency has since revised the guidance to provide the option of submitting an abbreviated 510(k), thereby reducing the burden. At the same time, FDA is revising the title of the document to ''Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA.''

Interested persons were invited to comment on the proposed rule by August 7, 2001. FDA received one comment. That comment commended FDA's proposal to reclassify ADCCs into class II and agreed that the guidance proposed as the special control was adequate to provide reasonable assurance of the safety and effectiveness of the device.

II. FDA's Conclusion

Based on a review of the available information, referenced in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA concludes that special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of this device.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA'' via your fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt, press 1 to access DSMICA Facts, at second voice prompt press 2, and then enter the document number (1184) followed by the pound sign (#). Then 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 a Web site at http://www.fda.gov/cdrh on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH Web site includes 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 medical device-oriented information. The CDRH Web site also includes the document ''Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA'' which may be accessed at http://www.fda.gov/cdrh/ode/guidance/1184.html. A search capability for all guidance documents may be found at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available at http://www.fda.gov/ohrms/dockets.

IV. 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.

V. Analysis of Impacts

FDA has examined the impacts of the final 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule 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 ADCCs from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e).

Moreover, compliance with special controls proposed for this device will not impose significant new costs on affected manufacturers because most of

these devices already comply with the proposed special controls. Because reclassification will reduce regulatory costs with respect to ADCCs, 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 final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule 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 of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

List of Subjects in 21 CFR Part 864

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

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 document entitled ''Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA.''

Dated: January 3, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–792 Filed 1–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–02–001]

Drawbridge Operation Regulations; 63rd Street Bridge, Indian Creek, Mile 4.0, Miami Beach, Miami-Dade County, FL

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the 63rd Street Bridge across Indian Creek, mile 4.0, Miami Beach, Miami-Dade County, Florida. This deviation allows the drawbridge owner or operator to not open the Bridge from January 15, 2002 to January 19, 2002. This temporary deviation is required to allow the bridge owner to safely complete repairs to the Bridge.

DATES: This deviation is effective from 12:01 a.m. on January 15, 2002 until 11:59 p.m. on January 19, 2002.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Miami, FL 33131 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Chief, Operations Section, Seventh Coast Guard District, Bridge Section at (305) 415–6743.

SUPPLEMENTARY INFORMATION: The 63rd Street Bridge across Indian Creek, Miami Beach, Miami-Dade County, Florida is a double leaf bridge with a vertical clearance of 11.0 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 50 feet. On December 21, 2001, the Florida Department of Transportation, the drawbridge owner, requested a deviation from the current operating regulation in 33 CFR part 117 which requires the draw of the 63rd Street Bridge, mile 4.04 at Miami Beach, to open on signal. This temporary deviation was requested to allow necessary repairs to the drawbridge in a critical time sensitive manner.

The District Commander has granted a temporary deviation from the operating requirements listed in 33 CFR part 117 to complete repairs to the drawbridge. Under this deviation, the 63rd Street Bridge need not open either span from 12:01 a.m. on January 15, 2002 until 11:59 p.m. on January 19, 2002.

Dated: January 7, 2002.

Greg E. Shapley,

Chief, Bridge Administration, Seventh Coast Guard District.

[FR Doc. 02–859 Filed 1–11–02; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

CGD01–01–211

RIN 2115–AA97

Safety and Security Zone; Pilgrim Nuclear Power Plant, Plymouth, MA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety and security zones around the Pilgrim Nuclear Power Plant in Cape Cod Bay, Plymouth, MA from November 15, 2001 until June 15, 2002. The safety and security zones will temporarily close all waters within an approximate 1000-yard distance from the plant, and will also close shore areas adjacent to the plant. The safety and security zones prohibit entry into or movement within a portion of Cape Cod Bay and adjacent shore