agency modified the name of the generic type of device and its identification to make it clear that the rule applies to two groups of devices, blood mixing devices and blood weighing devices that are intended for medical purposes. Accordingly, the proposed regulation is being adopted with the changes noted.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart J by adding new § 864.9195, to read as follows:

§ 864.9195 Blood mixing devices and blood weighing devices.

(a) *Identification.* A blood mixing device is a device intended for medical purposes that is used to mix blood or blood components by agitation. A blood weighing device is a device intended for medical purposes that is used to weigh blood or blood components as they are collected.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 14, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27387 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1926]

Classification of Blood and Plasma Warming Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying nonelectromagnetic blood and plasma warming devices into class II (performance standards) and electromagnetic blood and plasma warming devices into class III (premarket approval). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each premarket approval application must be submitted to FDA on or before April 29, 1983, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the Federal Register of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel and the Pathology Device Classification Panel). FDA also published in that issue of the Federal Register (44 FR 53047) a proposed regulation to classify nonelectromagnetic blood and plasma warming devices into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart J by adding new § 864.9205, to read as follows:

§ 864.9205 Blood and plasma warming device.

(a) *Nonelectromagnetic blood or plasma warming device*—(1) *Identification.* A nonelectromagnetic blood and plasma warming device is a device that warms blood or plasma, by means other than electromagnetic radiation, prior to administration.

(2) *Classification.* Class II (performance standards).

(b) *Electromagnetic blood and plasma warming device*—(1) *Identification.* An electromagnetic blood and plasma warming device is a device that employs electromagnetic radiation (radiowaves or microwaves) to warm a bag or bottle of blood or plasma prior to administration.

(2) *Classfication.* Class III (premarket approval).

Effective date. This regulation shall be effective October 14, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27388 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1927]

Classification of Cell-Freezing Apparatus and Reagents for In Vitro Diagnostic Use

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cell-freezing apparatus and reagents for in vitro diagnostic use into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel and the Pathology Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 53050) a proposed regulation to classify cell-freezing apparatus and reagents for in vitro diagnostic use into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart J by adding new § 864.9225, to read as follows:

§ 864.9225 Cell-freezing apparatus and reagents for in vitro diagnostic use.

(a) *Identification.* Cell-freezing apparatus and reagents for in vitro diagnostic use are devices used to freeze human red blood cells for in vitro diagnostic use.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 24, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27389 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N–1928]

Classification of Automated Blood Cell Separators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying automated blood cell separators into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. Each application must be submitted to FDA on or before April 29, 1983, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel and the Pathology Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 53050) a proposed regulation to classify automated blood cell separators into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

The following is a summary of the comments received on the proposal and the agency's response to them:

1. A comment from the Haemonetics Corp., a manufacturer of automated blood cell separators, agreed that automated blood cell separators should be classified into class III. The comment requested that the regulation distinguish cell separators with reusable bowls from cell separators with disposable bowls. The comment noted that the Panel recommendations are appropriate for systems employing reusable bowls but not for systems employing disposable bowls. The comment stated that cell separators with completely disposable blood pathways do not present a potential unreasonable risk of illness or injury nor are these devices life threatening. Cross contamination is not a problem with presterilized blood pathways that are disposed of after use. The comment noted that Haemonetics' 7 years of experience with automated blood cell separators, involving over 1 million blood processing procedures, had not resulted in a single report of infection or biologic reaction due to contamination within the disposable blood pathway. It was also noted that there has been no evidence of donor or recipient harm due to blood incompatibility caused by the materials in the disposable blood pathways. The comment provided additional references concerning disposable systems, noting that the references published with the proposed regulation dealt only with cell separators with reusable bowls.

FDA agrees that the regulation should distinguish disposable pathway devices from reusable bowl devices, as well as filtration leukapheresis devices. Therefore, the identification has been modified to reflect this distinction. FDA agrees that contamination is not a problem with disposable blood pathways if their sterility is assured. However, the risks of shock, blood loss, clotting, exposure to hepatitis, and delivery of damaged blood components still constitute a potential unreasonable risk of illness or injury. FDA agrees that the references provided with the proposed regulation refer only to reusable bowl devices. Therefore, an additional reference has been provided with the final regulation (Ref. 5).

2. Travenol Laboratories, another manufacturer of automated blood cell separators, stated that sufficient information exists to write a performance standard for automated blood cell separators and that the Panel was not aware of this information when it recommended classification into class III. The comment claimed that the Panel had, therefore, placed these devices in class III by default. The comment noted that certain risks to the donor, i.e.

activation of the complement systems, abdominal pain, heparin toxicity, and fever in recipient patients, are associated only with filtration leukapheresis and not centrifugal cell separation. The comment stated that filtration leukapheresis is almost nonexistent in the United States and therefore risks associated with filtration leukapheresis are not associated with automated blood cell separators. Travenol stated that it is unaware of the Panel's experience with severe fevers in patients due to pump-induced breakdown of granulocytes or severe bleeding in patients after infusion of white cells prepared with an automated cell separator, and suggested that these problems be reported to the manufacturer or published in a scientific journal. The comment questioned that the references cited in the proposal to the proposed regulation supported the agency's action. The thromboembolism problems cited in reference 1 was said to be due to the improper choice of anticoagulant, not to cell separator malfunction, and was solved by the use of a micro-aggregate filter. The sterilization problem cited in reference 2 were said to be due largely to reusable bowls. The use of sterilized disposable bowls and fluid pathways have eliminated these problems. Reference 3 was said to refer to a complete plasma exchange transfusion and not to routine component donations. Reference 4 (21 CFR Part 606.65) is a regulation administered by the Bureau of Biologics, FDA, through its licensure programs, CGMP inspections of licensed establishments, and master file requirements. Travenol believes that premarket approval is unnecessary due to the controls already in existence to assure safety and effectiveness. The comment agreed that the use of the automated blood cell separator to prepare blood components for transfusion is of substantial importance in preventing impairment of human health. The comment asserted, however, that the device does not present a potential unreasonable risk to health, and it is not an implant, life sustaining, or life supporting.

FDA does not agree that there is sufficient information to establish a performance standard for these devices. The Panel did not recommend placing these devices into class III "by default" due to unfamiliarity with available information. Rather, the Panel based its recommendation on its members' experience with these devices, including the experience of a member who is a blood banker. FDA agrees that certain risks cited in the proposed regulation apply only to filtration leukapheresis devices. However, FDA has no data to support the comment's assertion that filtration leukapheresis is almost nonexistent in the United States. Therefore, a consideration of filtration devices and their associated risks is appropriate to a discussion of automated blood cell separators. FDA agrees with the comments concerning references 1 and 2 of the proposed regulation. Concerning reference 3, FDA notes that at least one automated blood cell separator is promoted for use in plasma exchanges. Because the use of an automated blood cell separator can be of substantial importance in preventing impairment of human health and because insufficient information exists to write a performance standard, premarket approval is necessary to provide a reasonable assurance of the safety and effectiveness of automated blood cell separators.

FDA thus disagrees with the comment's suggestion that automated blood cell separators be classified into class II and is classifying the device into class III as proposed.

On November 19, 1979, FDA held a public meeting of the Hematology Section of the Clinical Chemistry and Hematology Devices Panel at which the comments received on the proposal were considered. At the meeting, representatives of Travenol Laboratories presented their views that these devices should be classified into class II.

FDA has carefully considered the comments, and the additional information and data submitted on this device, and the Section's recommendation that automated blood cell separators be classified into class III as proposed. FDA believes that insufficient information exists to establish a performance standard for the device and that its use is of substantial importance in preventing impairment of human health.

Potential problems with the device such as clotting in the bowl, leaks in the system, fainting, nausea and convulsions, still exist. Alarm systems are built into the newer machines precisely because these problems can still occur. The danger can be even greater if individuals using the device rely upon the alarm system, and the system malfunctions. Problems with automated blood cell separators may be underestimated due to a reluctance on the part of investigators to publish a description of the difficulties they have encountered. Concerns over the potential risk to the donor have also been expressed because automated blood cell separators are used increasingly for leukapheresis. McCullough (Ref. 6) believes that additional clinical studies will be required to determine the effects of leukapheresis on normal donors. FDA believes that until these studies are completed, the safety and effectiveness of this device have not been established. Therefore, premarket approval is necessary to provide a reasonable assurance of the device's safety and effectiveness.

Accordingly, the proposed regulation is being adopted with the changes noted.

List of References

1. Moriau, M., M. De Bruyere, and C. Bellenot, "Granulocyte Collections From Normal Donors Using the Continuous Flow Centrifuge," *in "Leukocytes:* Separation, Collection, and Transfusion," Edited by Goldman, J. M. and R. M. Lowenthal, Academic Press, London, pp. 88–96, 1975.

2. Cartledge, K. W., "Problems in the Sterilization of Cell Separator Bowls," *in "Leukocytes:* Separation, Collection, and Transfusion," Edited by Goldman, J. M. and R. M. Lowenthal, Academic Press, London, pp. 43–45, 1975.

3. Oon, C. J. and J. R. Hobbs, "Medical Problems in Donors on Treatment Using the Continuous Flow Blood Separator," *in* "Leukocytes: Separation, Collection, and Transfusion," Edited by Goldman, J. M. and R. M. Lowenthal, Academic Press, London, pp. 576–577, 1975.

4. Code of Federal Regulations, 21 CFR Part 606—Current Good Manufacturing Practices for Blood and Blood Components, Subpart D—Equipment § 606.65.

5. Hester, J. P. et al., "Principals of Blood Separation and Component Extraction in a Disposable Continuous-Flow Single Stage Channel," *Blood,* 54(1):254–268, 1979.

6. McCullough, J., "Leukapheresis and Granulocyte Transfusion," *CRC Critical Reviews in Clinical Laboratory Sciences:* 275–327, 1979.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart J by adding new § 864.9245, to read as follows:

§ 864.9245 Automated blood cell separator.

(a) *Identification.* An automated blood cell separator is a device that automatically removes whole blood from a donor, separates the blood into components (red blood cells, white blood cells, plasma, and platelets), retains one or more of the components, and returns the remainder of the blood to the donor. The components obtained are transfused or used to prepare blood products for administration. These devices operate on either a centrifugal separation principle or a filtration principle. The separation bowls of centrifugal blood cell separators may be reusable or disposable.

(b) *Classification.* Class IIII (premarket approval).

Effective date. This regulation shall be effective October 14, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27390 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1929]

Classification of Blood Bank Centrifuges for in Vitro Diagnostic Use

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying blood bank centrifuges for in vitro diagnostic use into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel the Pathology Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 53052) a proposed regulation to classify blood bank centrifuges for in vitro diagnostic use into class I (general controls). A period of 60 days was provided for interested persons to submit written comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs is amending Part 864 in Subpart J by adding new § 864.9275, to read as follows:

§ 864.9275 Blood bank centrifuge for in vitro diagnostic use.

(a) *Identification.* A blood bank centrifuge for in vitro diagnostic use is a device used only to separate blood cells for further diagnostic testing.

(b) *Classification.* Class I (general controls).

Effective date. This regulation shall be effective October 14, 1980.

(Secs.513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)))

Dated: August 15, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-27391 Filed 9-11-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 864

[Docket No. 78N-1930]

Classification of Automated Cell-Washing Centrifuges for Immuno-Hematology

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying automated cell-washing centrifuges for immuno-hematology into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: October 14, 1980.

FOR FURTHER INFORMATION CONTACT: Kaiser Aziz, Bureau of Medical Devices (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of September 11, 1979 (44 FR 52950), a proposed regulation explaining the development of the proposed regulations classifying hematology and pathology devices, the medical device classification procedures, and the activities of the Hematology and Pathology Device Section of the Clinical Chemistry and Hematology Devices Panel (formerly the Hematology Device Classification Panel and the Pathology Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 53052) a proposed regulation to classify automated cell-washing centrifuges for immuno-hematology into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted without change.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions,