Panel). FDA also published in that issue of the **Federal Register** (44 FR 49939) a proposed regulation to classify protective restraints into class I (general controls). A period of 60 days was provided for interested persons to submit comments to FDA.

Two comments were received. The comments agreed with the proposed classification and proposed exemption for protective restraints. Accordingly, the proposed regulation is being adopted with a minor clarifying 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 880 in Subpart G by adding new § 880.6760, to read as follows:

§ 880.6760 Protective Restraint.

(a) *Identification.* A protective restraint is a device, usually a wristlet, anklet, or other type of strap, that is intended for medical purposes and that limits a patient's movements to the extent necessary for treatment, examination, or protection of the patient.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is also exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-31620 Filed 10-20-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 880

[Docket No. 78N-1359]

General Hospital and Personal Use Devices; Classification of Powered Patient Transfer Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying powered patient transfer devices 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: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (44 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49941) a proposed regulation to classify AC-powered patient transfer devices 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. However, the agency has made minor changes in the name and identification of the device to clarify the range of devices included in the generic class covered by this rule. Accordingly, the proposed regulation is being adopted with these changes.

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 880 in Subpart G by adding new § 880.6775, to read as follows:

§ 880.6775 Powered patient transfer device.

(a) *Identification.* A powered patient transfer device is a device consisting of a wheeled stretcher and a powered mechanism that has a broad, flexible band stretched over long rollers that can advance itself under a patient and transfer the patient with minimal disturbance in a horizontal position to the stretcher.

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

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-31621 Filed 10-20-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 880

[Docket No. 78N-1360]

General Hospital and Personal Use Devices; Classification of Manual Patient Transfer Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying manual patient transfer devices into class I (general controls) and exempting manufacturers of the device from premarket notification procedures and certain requirements of the good manufacturing practice regulation. The effect of this rule is to require that the device meet only the general controls applicable to all devices, except for the premarket notification procedures and certain requirements of the good manufacturing practice regulation. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (44 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49941) a proposed regulation to classify manual patient transfer devices 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 880 in Subpart G by adding new § 880.6785, to read as follows:

§ 880.6785 Manual patient transfer device.

(a) *Identification.* A manual patient transfer device is a device consisting of a wheeled stretcher and a mechanism on which a patient can be placed so that the patient can be transferred with minimal disturbance in a horizontal position to the stretcher.

(b) *Classification.* Class I (general controls). The device is exempt from premarket notification procedures in Subpart E of Part 807. The divice also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–31622 Filed 10–20–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 880

[Docket No. 78N–1361]

General Hospital and Personal Use Devices; Classification of Washers for Body Waste Receptacles

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying washers for body waste receptacles into class I (general controls) and exempting manufacturers of the device from premarket notification procedures and certain requirements of the good manufacturing practice regulation. The effect of this rule is to require that the device meet only the general controls applicable to all devices, except for the premarket notification procedures and certain requirements of the good manufacturing practice regulation. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (44 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49942) a proposed regulation to classify washers for body waste receptacles into class I (general controls). A period of 60 days was provided for interested persons to submit comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device. Accordingly, the proposed regulation is being adopted with only minor clarifying changes.

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 880 in Subpart G by adding new § 880.6800, to read as follows:

§ 880.6800 Washers for body waste receptacles.

(a) *Identification.* A washer for body waste receptacles is a device intended for medical purposes that is used to clean and sanitize a body waste receptacle, such as a bedpan. The device consists of a wall-mounted plumbing fixture with a door through which a body waste receptacle is inserted. When the door is closed the body waste receptacle is cleaned by hot water, steam, or germicide.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–31623 Filed 10–20–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 880

[Docket No. 78N-1362]

General Hospital and Personal Use Devices; Classification of Medical Disposable Scissors

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying medical disposable scissors into class I (general controls) and exempting manufacturers of the device from premarket notification procedures. The effect of this rule is to require that the device meet only the general controls applicable to all devices, except for the premarket notification procedures. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (44 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49944) a proposed regulation to classify medical disposable scissors into class I (general controls). A period of 60 days was provided for comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. However, the agency has made minor changes in the name and identification of the device to make it clear that the rule applies only to those devices that are intended for medical purposes. Accordingly, the proposed regulation is being adopted with these changes.

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 the commissioner of Food and Drugs (21 CFR 5.1), Part 880 is amended in Subpart G by adding new § 880.6820, to read as follows:

§ 880.6820 Medical disposable scissors.

(a) *Identification.* Medical disposable scissors are disposable type general cutting devices intended for medical purposes. This generic type of device does not include surgical scissors.

(b) *Classification.* Class I (general controls). The device is exempt from premarket notification procedures in Subpart E of Part 807.

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-31624 Filed 10-20-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 880

[Docket No. 78N-1363]

General Hospital and Personal Use Devices; Classification of Sterilization Wraps

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying sterilization wraps 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: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (4 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49945) a proposed regulation to classify sterilization wraps into class II (performance standards). A period of 60 days was provided for interested persons to submit comments to FDA.

One comment was received. The comment agreed with the proposal to classify sterilization wraps into class II.

The agency has made minor changes to the identification of the device to clarify that the rule applies only to those sterilization wraps that are intended for use by health care providers, such as hospitals and physicians. Accordingly, the proposed regulation is being adopted with these changes.

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 880 in Subpart G by adding new § 880.6850, to read as follows:

§ 880.6850 Sterilization wrap.

(a) *Identification.* A sterilization wrap (pack, sterilization wrapper, bag, or accessories, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

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

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-31625 Filed 10-20-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 880

[Docket No. 78N-1364]

General Hospital and Personal Use Devices; Classification of Ethylene Oxide Gas Sterilizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying ethylene oxide gas sterilizers 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: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (44 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49946) a proposed regulation to classify ethylene oxide gas sterilizers into class II (performance standards). A period of 60 days was provided for interested persons to submit comments to FDA.

A comment from the United States Environmental Protection Agency (EPA) stated that ethylene oxide gas (ETO) sterilant is currently regulated by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA regulates self-contained portable ETO gas sterilizers and these portable sterilizers are registered with EPA. This registration involves a preregistration efficacy evaluation and a hazard evaluation with respect to the operation of the device. EPA believes that FDA's regulation delineate clearly the responsibilities of the two agencies.

FDA and EPA are currently discussing the regulation of this device and its accessories and will develop and publish in the **Federal Register** a Memorandum of Understanding concerning each agency's responsibility for the regulation of this device. Until the Memorandum of Understanding is published, EPA will continue to be principally responsible for regulating ETO sterilants and self-contained portable ETO gas sterilizers. FDA will be principally responsible for regulating nonportable ETO gas sterilizers which are intended for use by health care providers, such as hospitals and physicians, for sterilizing medical products. In the **Federal Register** of June 23, 1978, FDA published a proposed rule that would impose restrictions on the continued use of ETO as a sterilant for certain drug products and medical devices for human use. Accordingly, the proposed regulation is being adopted with these changes.

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), to the Commissioner of Food and Drugs is amending Part 880 in Subpart G by adding new § 880.6860, to read as follows:

§ 880.6860 Ethylene oxide gas sterilizer.

(a) *Identification.* An ethylene gas sterilizer is a nonportable device intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical products.

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

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-31626 Filed 10-20-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 880

[Docket No. 78N-1365]

General Hospital and Personal Use Devices; Classification of Dry-Heat Sterilizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying dry-heat sterilizers 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: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (44 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49947) a proposed regulation to classify dry-heat sterilizers into class II (performance standards). A period of 60 days was provided for interested persons to submit comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. However, the agency has made minor changes in the identification of the device to clarify that the rule applies only to those dry-heat sterilizers that are intended for use by a health care provider. Accordingly, the proposed regulation is being adopted with these changes.

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 880 in Subpart G by adding new § 880.6870, to read as follows:

§ 880.6870 Dry-heat sterilizer.

(a) *Identification.* A dry-heat sterilizer is a device that is intended for use by a health care provider to sterilize medical products by means of dry heat.

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

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-31627 Filed 10-20-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 880

[Docket No. 78N-1366]

General Hospital and Personal Use Devices; Classification of Steam Sterilizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying steam sterilizers 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: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (44 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49948) a proposed regulation to classify steam sterilizers into class II (performance standards). A period of 60 days was provided for interested persons to submit comments to FDA.

No comments have been received regarding the proposed regulation to classify this device. However, the agency has made minor changes in the identification of the device to clarify that the rule applies only to those devices that are intended for use by a health care provider. Accordingly, the proposed regulation is being adopted with these changes.

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 880 in Subpart G by adding new § 880.6880, to read as follows:

§ 880.6880 Steam sterilizer.

(a) *Identification.* A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam.

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

Effective date. This regulation shall be effective November 20, 1980.

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

Dated: September 17, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-31628 Filed 10-20-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 880

[Docket No. 78N-1367]

General Hospital and Personal Use Devices; Classification of Hand-Carried Stretchers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying hand-carried stretchers into class I (general controls) and exempting manufacturers of the device from certain requirements of the good manufacturing practice regulation. The effect of this rule is to require that the device meet only the general controls applicable to all devices, except for certain requirements of the good manufacturing practice regulation. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Lillian L. Yin, Bureau of Medical Devices (HFK–470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of August 24, 1979 (44 FR 49844), a proposed regulation explaining the development of the proposed regulations classifying general hospital and personal use devices, the medical device classification procedures, and the activities of the General Hospital and Personal Use Device Section of the General Medical Devices Panel (formerly the General Hospital and Personal Use Device Classification Panel). FDA also published in that issue of the **Federal Register** (44 FR 49949) a proposed regulation to classify hand-carried stretchers 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.