

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying patient care suction apparatus 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: March 6, 1980.

FOR FURTHER INFORMATION CONTACT: John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: FDA published in the *Federal Register* of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the *Federal Register* (44 FR 13421) a proposed regulation to classify patient care suction apparatus into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

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

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 870 by adding Subpart F and new § 870.5050, to read as follows:

Subpart F—Cardiovascular Therapeutic Devices

§ 870.5050 Patient care suction apparatus.

(a) *Identification.* A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

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

Effective date. This regulation shall be effective March 6, 1980.

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

Dated: January 14, 1980.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 80-3333 Filed 2-4-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 870

[Docket No. 78N-1539]

Cardiovascular Devices; Classification of Embolectomy Catheters

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying embolectomy catheters 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: March 6, 1980.

FOR FURTHER INFORMATION CONTACT: John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: FDA published in the *Federal Register* of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the *Federal Register* (44 FR 13422) a proposed regulation to classify embolectomy catheters into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

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

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 870 in Subpart F by adding new § 870.5150, to read as follows:

§ 870.5150 Embolectomy catheter.

(a) *Identification.* An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated in blood vessels from one site in the vascular tree to another.

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

Effective date. This regulation shall be effective March 6, 1980.

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

Dated: January 14, 1980.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 80-3334 Filed 2-4-80; 8:45 am]

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21 CFR Part 870

[Docket No. 78N-1540]

Cardiovascular Devices; Classification of Septostomy Catheters

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying septostomy catheters 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: March 6, 1980.

FOR FURTHER INFORMATION CONTACT: John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: FDA published in the *Federal Register* of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the *Federal Register* (44 FR 13423) a proposed regulation to classify septostomy catheters into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

No written comments have been received regarding the proposed regulation to classify this device.

Accordingly, the proposed regulation is being adopted without change.

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 870 in Subpart F by adding new § 870.4280, to read as follows:

§ 870.5175 Septostomy catheter.

(a) *Identification.* A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of certain infants.

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

Effective date. This regulation shall be effective March 6, 1980.

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

Dated: January 14, 1980.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 80-3335 Filed 2-4-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 870

[Docket No. 78N-1541]

Cardiovascular Devices; Classification of External Cardiac Compressors

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying external cardiac compressors 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 September 30, 1982, 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: March 6, 1980.

FOR FURTHER INFORMATION CONTACT: John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: FDA published in the *Federal Register* of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the *Federal Register* (44 FR 13424) a proposed regulation to classify external cardiac compressors into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

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

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 870 in Subpart F by adding new § 870.5200, to read as follows:

§ 870.5200 External cardiac compressor.

(a) *Identification.* An external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest.

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

Effective date. This regulation shall be effective March 6, 1980.

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

Dated: January 14, 1980.

William F. Randolph,
*Acting Associate Commissioner for
Regulatory Affairs.*

[FR Doc. 80-3336 Filed 2-4-80; 8:45 am]

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21 CFR Part 870

[Docket No. 78N-1542]

Cardiovascular Devices; Classification of External Counter-Pulsating Devices

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying external counter-pulsating devices 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 September 30, 1982, 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: March 6, 1982.

FOR FURTHER INFORMATION CONTACT: John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: FDA published in the *Federal Register* of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the *Federal Register* (44 FR 13426) a proposed regulation to classify external counter-pulsating devices into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

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

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 870 in Subpart F by adding new § 870.5225, to read as follows:

§ 870.5225 External counter-pulsating device.

(a) *Identification.* An external counter-pulsating device is a noninvasive device used to assist the heart by applying positive or negative pressure to one or more of the body's limbs in synchrony with the heart cycle.

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

Effective date. This regulation shall be effective March 6, 1980.

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

Dated: January 14, 1980.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 80-3337 Filed 2-4-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 870

[Docket No. 78N-1543]

Cardiovascular Devices; Classification of DC-Defibrillators (Including Paddles)

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying low-energy DC-defibrillators into class II (performance standards) and high-energy DC-defibrillators 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 application for premarket approval for high-energy DC-defibrillators must be submitted to FDA on or before September 30, 1982, 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: March 6, 1980.

FOR FURTHER INFORMATION CONTACT: John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: FDA published in the Federal Register of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the Federal Register (44 FR 13426) a proposed regulation to classify DC-defibrillators (including paddles) into class III (premarket approval). A period of 60 days was provided for interested persons to submit comments to FDA.

FDA received two general comments on the proposed regulation for DC-defibrillators, which made no suggestion regarding the proposed classification:

1. Dr. Leslie Geddes, a former panel member, stated that he believes that he was misquoted in the proposed regulation. He said he would never state that 15 times threshold energy is safe; he believes that 1.5 times threshold energy is safe.

The proposed regulation stated that "damage (in dogs) occurs at 15 times defibrillation threshold." This statement was made during a panel meeting at which dose-response curves were being discussed. According to that discussion, the ED 50 (50 percent effected dose) is 1 joule per kilogram, and the TD 50 (50 percent toxic dose) is 15 joules per kilogram. Toxic dose was defined as any histopathologic damage, not as functional damage. FDA agrees with the comment that the proposal incorrectly implies that energy levels below 15 times the defibrillation threshold are safe.

2. One comment stated that additional data should be considered during final classification of DC-defibrillators. The comment discussed ongoing research involving 41 patients who underwent emergency ventricular defibrillation by a defibrillator with a maximum output of 460 joules delivered energy. Of the 41 patients, 15 required multiple shocks of 400 joules or greater for eventual successful defibrillation. Four patients required 2 shocks at 400 joules, 3 patients required 3 shocks at 400 joules, 6 patients required 4 or more shocks at 400 joules, 1 patient required 2 shocks at 460 joules, and 1 patient required 4 shocks at 460 joules. The 2 patients who required 460-joule shocks did not defibrillate at lower energy levels. The comment said the question of potential damage did not arise and that this energy level was required for the patients' survival.

The classification of DC-defibrillators was a controversial issue during the Circulatory System Devices Panel deliberations on device classification. The following comments were received on the proposed classification of DC-defibrillators into Class III. While all of the comments suggested that the classification of DC-defibrillators be changed, the form of the suggested change varied from comment to comment, as described below:

1. A comment suggested that the available data on defibrillation are not as contradictory as they may have appeared in the proposed regulation. In fact, the data actually support a divided classification. The comment noted that theoretical models have been

constructed showing that energy and density standards can be developed to ensure reasonably safe and effective defibrillator performance. Many variables affect defibrillation, including wave shape, duration, paddle size and position, drug usage (lidocaine, for example), time between the onset of fibrillation and the first defibrillation attempt, paddle pressure, the electrode paste used, transthoracic dimensions, heart dimensions, and physiologic state of the heart.

Based on experiments conducted on human hearts, it is possible to determine the energy needed for defibrillating human subjects. The comment provided references to show that 10 watt-seconds applied directly across the heart have been used to defibrillate most human hearts, but that occasionally 20 watt-seconds energy have been required. Ten to twenty watt-seconds energy delivered directly across a 500-gram heart, as described in the comment, is equivalent to: (a) 145 to 465 watt-seconds applied transthoracically; (b) a current density of 100 to 180 milliamperes per square centimeter; and (c) a peak current of 32 to 61 amperes.

The comment stated that classifying all defibrillators into class III is not likely to produce definitive answers to the questions of risk. The comment referred to the two theories in FDA's proposed classification regarding the energy required for defibrillation. The first is a dose concept relating defibrillation energy to body weight, and the second states that the energy required for defibrillation is not weight dependent. The comment proposed that the agency allow for a third theory that assumes that certain current densities in the heart are necessary for successful defibrillation and that these are dependent upon heart dimensions and the heart's location in the chest cavity.

The comment noted that it is not surprising that some researchers have obtained data correlating defibrillation energies to weight because heavier patients will tend to have greater chest dimensions and a resulting lower current density in the heart. On the other hand, the comment noted that variables other than weight are significant, such as the quality of the basic life-support systems used, physiological state of the heart, position of the heart within the chest cavity, heart size, area of the electrodes, electrode position with respect to the heart, resistivity of the electrode-patient interface, and the previous use of antiarrhythmic drugs. Therefore, the comment concluded, it is not surprising that some researchers have found no

correlation between body weight and the required energy for defibrillation.

The comment stated that medical judgment is necessary when using defibrillators and that device labeling can provide information to guide the exercise of medical judgment. The comment also stated that electrical design and paddle position and design have been addressed in the FDA Draft Defibrillator Standard and in the literature referenced in the comment. The comment stated that the remaining concerns of risks to health are medical concerns that can be addressed by labeling and noted that defibrillators with delivered energy of 400 watt-seconds may be needed to defibrillate patients whose hearts would require 20-watt-seconds energy shocks directly across the heart. The comment stated that based on the information available, an upper energy level can be determined for damped sinusoidal waveforms and a standard would assure reasonable safety and performance.

2. Another comment urged FDA not to classify all defibrillators into class III, but recommended that the Panel and the agency determine which waveforms have been shown to be adequately safe and effective and place those waveforms into class II. The comment said there is little difference of opinion among most of the scientists who were asked about the maximum energy level that would divide "high available energy" defibrillators from "traditional energy" defibrillators and that a number of experts believe that the energy level that divides the "high energy" from "traditional energy" defibrillators is between 320 joules and 400 joules delivered energy, a difference of only 20 percent. This represents even less difference in terms of current output, according to the comment.

3. A comment simply recommended that a split in the classification of defibrillators be considered and that 400 joules seems to be an appropriate upper limit for classification into class II.

4. A comment presented data accumulated in prospective investigations of cross-chest ventricular defibrillation in humans showing that devices which store no more than 400 joules, deliver a maximum shock of between 250 joules (trapezoidal wave) and 360 joules (damped sine wave) via a 50-ohm test load defibrillate at an efficiency of 95 to 99 percent. Therefore, the comment suggested that defibrillators with these levels of performance be classified into class II and that defibrillators that store more than 400 joules or deliver a maximum shock over 360 joules or under 250 joules for cross-chest defibrillation are truly

experimental medical devices and belong in class III. The comment also offered views on the summary of the panel recommendation that accompanied the proposed classification and suggested that the proposal should have cited several additional references (Refs. 1 through 4).

5. A comment referenced personal work involving direct-current counter shock in animal models performed during the past year. This work is published in the *American Journal of Cardiology*, February 1979 (Ref. 5). It demonstrates that a number of factors relating to energy level, the size of the paddles, and interval between shocks are important in producing cardiac damage. The pathophysiology appears to be thermal damage in large part.

Based on the commenter's experience and the animal work, the following comments were made:

a. Damped-sinusoidal (Lown) waveform defibrillators that deliver less than 400 joules energy have been demonstrated to be highly effective and relatively safe. Repeated use in patients does produce myocardial damage, but this is due to the type of heart disease being treated, the need for repeated shocks, and the multiple high-energy shocks that must be delivered.

b. The contradictory studies relating to the maximum energy that should be delivered are not very controversial. When hearts are extremely large, energy levels slightly higher than 400 joules would be helpful. For the majority of patients, however, the kind of heart disease and the cardiac damage that has already been produced by the disease are the determinant factors. Except in unusual circumstances, 400 joules appears to be a high enough energy level for most patients.

6. A comment supported classification of all DC-defibrillators with delivered energies of 400 joules or less into class II. The comment stated that a standard can be developed based on available information and that such a standard would provide reasonable assurance of the safety and effectiveness of these DC-defibrillators. The comment also pointed out that FDA did not discuss in the proposal the significant human experience with marketed defibrillators over the past several years and stated that, for defibrillators in the range of 400 joules or less, ample evidence exists showing that benefits to health outweigh the probable risks.

7. One comment described certain experience with high-dose (400 and 460 joules) emergency defibrillation at a teaching hospital. A fairly substantial number of patients at that hospital have required high-energy shocks after the

same or lower energies failed to defibrillate them. The comment asserted these data are at variance with those of other investigators because of patient selection.

Many of the previously reported studies concentrated on patients defibrillated in coronary care units where there is a brief lapse of time between the onset of ventricular fibrillation and the first shock, where arrhythmias are primarily ventricular fibrillation, and where acidosis and hypoxia are minimal. The comment's experience is in a general hospital where the majority of patients are not in the coronary care unit, but are defibrillated on the general wards or after being brought into the hospital in an ambulance. The delays are greater with these patients, and therefore the patients are more hypoxic and acidotic.

8. Finally, two comments stated that defibrillators designed to deliver a damped sinusoidal waveform should be classified into class II if the stored energy level does not exceed 400 watt-seconds. These comments stated that the safety and efficacy of these defibrillators have been established by long clinical use and cite data summarized in a reprint from the *New England Journal of Medicine* (Ref. 6). These comments recommend that all other DC-defibrillators be classified into class III, including those damped sinusoidal waveforms with stored energies in excess of 400 watt-seconds and waveforms other than the damped sinusoidal waveforms.

FDA and its Circulatory System Devices Panel have reviewed the comments on the proposed classification of DC-defibrillators. FDA proposed to classify the device into class III primarily because of the disagreement among physicians concerning the benefit/risk assessment of low-energy versus high-energy defibrillation. FDA did not believe that enough data existed on which to base a class II classification for any defibrillator, given the medical disagreement regarding the benefits and risks of low-energy versus high-energy defibrillation. One apparent result of the proposed classification was to encourage efforts to achieve consensus on these issues. A proponent of high-energy defibrillation and a proponent of low-energy defibrillation have worked together with a committee of the Association for the Advancement of Medical Instrumentation (AAMI) and have now agreed on a uniform position on these issues. According to AAMI (Ref. 7), most researchers and clinicians actively working on defibrillation now believe that standards can be written for

all defibrillators with a maximum delivered energy between 250 and 360 joules, regardless of waveform.

It is important to note that, in this document, FDA is classifying only defibrillators of types that are currently on the market. Based on the information received last year from the Health Industry Manufacturers Association and on data in the literature, FDA finds that most marketed defibrillators of the damped sinusoidal type with delivered energies of 360 joules or less have peak currents in the range of 50 to 60 amperes and durations of between 3 and 7 milliseconds. The trapezoidal waveform reported in the literature has a 250-joule delivered energy and a peak current of approximately 24 amperes. Based on this general review of what is currently available on the market within the energy range specified above, FDA believes that the classification of defibrillators should be split as recommended by a letter following the comment period from AAMI Standards Committee. Accordingly, FDA is classifying into class II DC-defibrillators that deliver a maximizing 250 to 360 joules of energy into a 50-ohm test load, and into class III DC-defibrillators that deliver greater than 360 joules of energy into a 50-ohm test load. There are clinical data published by Crampton (Ref. 8) supporting the use of the damped sinusoidal waveforms and by Anderson and Suelzer (Ref. 1) for the trapezoidal waveform. Just as important as the existing animal and clinical data is the apparent agreement by most of the clinicians and researchers actively studying defibrillation that standards can be written for certain defibrillators.

FDA believes it is also important to state what this split in classification means:

a. Enough data exist on which to base a standard for all commercially available defibrillation waveforms with a maximum delivered energy between 250 and 360 joules. This does not mean that the defibrillators in this category represent the best tradeoff of benefit and risk as determined by paddle size and position and characteristics such as energy, current, and duration. It may be determined in the future that waveforms not included in this group may be the best waveforms for safe and effective defibrillation.

b. For defibrillators that are classified into class III, more data are needed to support a premarket approval application or a petition for reclassification.

c. Classification of certain defibrillators into class II requires that standards address not only energy but other important considerations, such as paddle size, and waveform

characteristics such as current and duration, and the variability of these waveform characteristics with differing chest impedances.

Accordingly, FDA is publishing a final regulation classifying low-energy DC-defibrillators into class II and high-energy DC-defibrillators into class III, dividing the devices in a manner consistent with the recommendation of the AAMI standards committee (Ref. 7). For the reasons stated in the general regulation on cardiovascular devices, published elsewhere in this issue of the *Federal Register*, FDA does not believe that it is necessary to issue a new proposal concerning this decision.

References

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2. Ehsani, A., G. A. Ewy, B. E. Sobel, "Effects of Electrical Countershock on Serum Creatine Phosphokinase (CPK) Isoenzyme Activity," *American Journal of Cardiology*, 37:12, 1976.
3. Jones, J. L., E. Lepeschkin, R. E. Jones, S. Rush, "Response of Cultured Myocardial Cells to Countershock-Type Electrical Field Stimulation," *American Journal of Physiology*, 235(2):H214, 1978.
4. Patton, N., J. F. Pantridge, "Current Required for Ventricular Defibrillation," *British Medical Journal*, 1:513, 1979.
5. Doherty, P. W., P. R. McLaughlin, M. Billingham, R. Kernoff, M. L. Goris, D. C. Harrison, "Cardiac Damage Produced by Direct Current Countershock Applied to the Heart," *American Journal of Cardiology*, 43:225-232, 1979.
6. Lown, B., R. S. Crampton, R. A. DeSilva, J. Gascho, "The Energy for Ventricular Defibrillation—Too Little or Too Much?" *New England Journal of Medicine*, 298(22):1252-1253, 1978.
7. Letter from John Gallagher and W. A. Tacker, Jr., MD, Ph.D., Cochairmen, AAMI Defibrillator Standards Committee, to Hearing Clerk, FDA, July 9, 1979.
8. Gascho, J. A., R. S. Crampton, M. L. Cherwek, J. N. Sipes, F. P. Hunter, W. M. O'Brien, "Determinants of Ventricular Defibrillation in Adults," *Circulation*, 60(2):231-240, August 1979.

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 870 in Subpart F by adding new § 870.5300, to read as follows:

§ 870.5300 DC-defibrillator (including paddles).

(a) *Low-energy DC-defibrillator—(1) Identification.* A low-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of

energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. This generic type of device includes low energy defibrillators with a maximum electrical output of less than 360 joules of energy that are used in pediatric defibrillation or in cardiac surgery. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

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

(b) *High-energy DC-defibrillator—(1) Identification.* A high-energy DC-defibrillator is a device that delivers into a 50 ohm test load an electrical shock of greater than 360 joules of energy used for defibrillating the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

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

Effective date. This regulation shall be effective March 6, 1980.

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

Dated: January 14, 1980.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

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21 CFR Part 870

[Docket No. 78N-1544]

Cardiovascular Devices; Classification of Defibrillator Testers

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying defibrillator testers 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: March 6, 1980.

FOR FURTHER INFORMATION CONTACT:

John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

FDA published in the Federal Register of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the Federal Register (44 FR 13429) a proposed regulation to classify defibrillator testers into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

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

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 870 in Subpart F by adding new § 870.5325, to read as follows:

§ 870.5325 Defibrillator tester.

(a) *Identification.* A defibrillator tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

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

Effective date. This regulation shall be effective March 6, 1980.

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

Dated: January 14, 1980.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 80-3339 Filed 2-4-80; 8:45 am]

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21 CFR Part 870

[Docket No. 78N-1545]

Cardiovascular Devices; Classification of External Transcutaneous Cardiac Pacemakers (Noninvasive)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying external transcutaneous cardiac pacemakers (noninvasive) 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 devices. Each application must be submitted to FDA on or before September 30, 1982, 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: March 6, 1980.

FOR FURTHER INFORMATION CONTACT:

John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: FDA published in the Federal Register of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the Federal Register (44 FR 13430) a proposed regulation to classify external transcutaneous cardiac pacemakers (noninvasive) into class III (premarket approval). A period 60 days was provided for interested persons to submit written comments to FDA.

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

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 870 in Subpart F by adding new § 870.5550, to read as follows:

§ 870.5550 External transcutaneous cardiac pacemaker (noninvasive).

(a) *Identification.* An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The pulse from the device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

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

Effective date. This regulation shall be effective March 6, 1980.

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

Dated: January 14, 1980.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 80-3340 Filed 2-4-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 870

[Docket No. 78N-1546]

Cardiovascular Devices; Classification of Compressible Limb Sleeves

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying compressible limb sleeves 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: March 6, 1980.

FOR FURTHER INFORMATION CONTACT:

John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: FDA published in the Federal Register of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the Federal Register (44 FR 13431) a proposed regulation to classify compressible limb sleeves into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

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

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