material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

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

Effective date. This regulation shall be effective October 4, 1979.

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

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26874 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1087]

Neurological Devices; Classification of Preformed Nonalterable Cranioplasty Plates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying preformed nonalterable cranioplasty plates 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 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55711) a proposed regulation to classify preformed nonalterable cranioplasty plates 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 882 in Subpart F by adding new § 882.5330, to read as follows:

§ 882.5330 Preformed nonalterable cranioplasty plate.

(a) *Identification.* A preformed nonalterable cranioplasty plate is a device that is implanted in a patient to repair a skull defect and is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

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

Effective date. This regulation shall be effective October 4, 1979.

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

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26875 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1088]

Neurological Devices; Classification of Cranioplasty Plate Fasteners

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cranioplasty plate fasteners 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 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55712) a proposed regulation to classify cranioplasty plate fasteners 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 882 in Subpart F by adding new § 882.5360, to read as follows:

§ 882.5360 Cranioplasty plate fastener.

(a) *Identification.* A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium, or stainless steel used to secure a plate to the patient's skull to repair a skull defect.

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

Effective date. This regulation shall be effective October 4, 1979.

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

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26876 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1089]

Neurological Devices; Classification of Lesion Temperature Monitors

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying lesion temperature monitors 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 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55713) a proposed regulation to classify lesion temperature monitors 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 882 in Subpart F by adding new § 882.5500, to read as follows:

§ 882.5500 Lesion temperature monitor.

(a) *Identification.* A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radiofrequency (RF) lesion generator and probe.

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

Effective date. This regulation shall be effective October 4, 1979.

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

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-28877 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 882

[Docket No. 78N-1090]

Neurological Devices; Classification of Central Nervous System Fluid Shunts and Components

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying central nervous system fluid shunts and components 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 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55714) a proposed regulation to classify central nervous system fluid shunts and components into class II (performance standards). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment objected to classifying central nervous system fluid shunts and components into class II (performance standards) and suggested that the device be classified into class III instead because not enough information exists to establish a performance standard.

The comment did not submit any additional data or information that was not considered by the agency before publishing the proposal to classify central nervous system fluid shunts and components into class II. Therefore, the agency rejects this comment.

A comment agreed with the proposal to classify implanted or partially implanted central nervous system fluid shunts and components into class II, but suggested that all components that are external to the patient (e.g., cerebrospinal fluid (CSF) collection bags) be classified into class I. The comment stated that medical costs could be reduced if bags designed for other purposes could be used for external CSF collection.

The agency has carefully considered this comment and has decided to classify all central nervous system fluid shunts and components in class II as proposed. The agency does not believe that classification of the device into class II will prevent the user from using other types of bags that were not specifically designed for CSF collection. The agency believes, however, that components specifically promoted for this purpose should be appropriate for the application and compatible with the other components used for central nervous system fluid shunting. The agency does not anticipate that a detailed performance standard for every component will be necessary. However, it does believe that a standard for central nervous system fluid shunt and components should address the compatibility of each component to the functioning of the overall system. 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 882 in Subpart F by adding new § 882.5550, to read as follows:

§ 882.5550 Central nervous system fluid shunts and components.

(a) *Identification.* A central nervous system fluid shunt is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

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

Effective date. This regulation shall be effective October 4, 1979.

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

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26878 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1091]

Neurological Devices; Classification of Cranial Electrotheraphy Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying cranial electrotheraphy stimulators 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 May 28, 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: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55716) a proposed regulation to classify cranial electrotheraphy stimulators 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 882 in Subpart F by adding new § 882.5800, to read as follows:

§ 882.5800 Cranial electrotheraphy stimulator.

(a) *Identification.* A cranial electrotheraphy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

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

Effective date. This regulation shall be effective October 4, 1979.

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

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26879 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1092]

Neurological Devices; Classification of External Functional Neuromuscular Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying external functional neuromuscular stimulators 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 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55717) a proposed regulation to classify external functional neuromuscular stimulators 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 882 in Subpart F by adding new § 882.5810, to read as follows:

§ 882.5810 External functional neuromuscular stimulator.

(a) *Identification.* An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

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

Effective date. This regulation shall be effective October 4, 1979.

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

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26880 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1093

Neurological Devices; Classification of Implanted Cerebellar Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted cerebellar stimulators 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 May 28, 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: October 4, 1979.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55718) a proposed regulation to classify implanted cerebellar stimulators into class III (premarket approval). A period of 60 days was provided for interested persons to submit written comments to FDA.

One comment disagreed with the proposal to classify implanted cerebellar stimulators in class III. The comment recommended that cerebellar stimulators for use in the treatment of spasticity be classified instead in class II because personal experience with over 100 patients had proven the safety and effectiveness of the device.

The Neurological Device Classification Panel received extensive testimony and data on cerebellar stimulation and concluded that insufficient information exists to establish a performance standard that would assure the safety and effectiveness of the device. The Panel, therefore, recommended that the device undergo premarket approval to assure that it is safe and effective. The comment received on the proposal to classify implanted cerebellar stimulators in class III did not provide additional data to show that a performance standard can be established that would assure the safety and effectiveness of implanted cerebellar stimulators. Therefore, the agency rejects the comment and is adopting the proposed regulation 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 882 in Subpart F by adding new § 882.5820, to read as follows:

§ 882.5820 Implanted cerebellar stimulator.

(a) *Identification.* An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

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

Effective date. This regulation shall be effective October 4, 1979.

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

Dated: August 17, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-26881 Filed 8-31-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 882

[Docket No. 78N-1094]

Neurological Devices; Classification of Implanted Diaphragmatic/Phrenic Nerve Stimulators

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying implanted diaphragmatic/phrenic nerve stimulators 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 May 28, 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: October 4, 1979.

SUPPLEMENTARY INFORMATION: FDA published in the **Federal Register** of November 28, 1978 (43 FR 55640) a proposed regulation explaining the development of the proposed regulations classifying neurological devices, the medical device classification procedures, and the activities of the Neurological Device Classification Panel. FDA also published in that issue of the **Federal Register** (43 FR 55719) a proposed regulation to classify implanted diaphragmatic/phrenic nerve stimulators 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 and the agency's responses to them:

1. One comment stated that this device should now be classified into class III so that manufacturers and users who are unfamiliar with the device will realize the need for caution in its construction and its application. The comment stated, however, that the device, as currently constructed, is reasonably safe and effective and that the principal risk to the patient is not from device failure but from the failure of the user to appreciate the indications for diaphragm pacing and from failure to apply the device properly.

FDA agrees with this comment.

2. A comment pointed out that the Neurological Device Classification Panel gave as a reason for classifying this device in class III the fact that available data on the device were from only one company. The comment stated that whether the device is available from one or more sources has no bearing on its safety and efficacy and enclosed a select bibliography of 59 references on diaphragm stimulation.

FDA agrees that the availability of a device from only one company does not mean that the device is not safe or effective. The Neurological Device Classification Panel did not recommend that this device be classified into class III solely because it is available from only one company. However, the Panel did cite this fact as one reason for believing that insufficient information is available to establish a performance standard for the device that will assure its safety and effectiveness. Because this device is a life-sustaining implant, the Federal Food, Drug, and Cosmetic Act requires that FDA classify it into class III if insufficient information is available to establish a performance standard that will assure the safety and effectiveness of the device. In this case, the agency concurs with the Panel that insufficient information exists to establish such a performance standard.

3. A comment was received regarding the risks to health identified by the Panel. The comment stated that device failure can be minimized, although not totally prevented, by using high quality components and production techniques and that the consequences of a catastrophic device failure can be ameliorated by using patient monitoring and device redundancy. The comment