Editor's Note. One of the objectives of the Journal is the exchange of information among members of all the disciplines involved in patient monitoring. This new section has been created with that objective in mind. Our intent is to provide readers with accurate, concise, and timely information pertaining to the regulation of medical devices. "FDA Report" will present summaries of important current topics regarding medical device regulation and procedures, relevant questions and answers, and "Letters to the FDA," correspondence to the Journal concerning the regulation of medical devices.

Suggestions of topics and questions to be addressed in this section, as well as "Letters to the FDA," may be submitted directly to one of the following individuals:

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Regulation of Medical Devices by the Food and Drug Administration
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The passage in 1976 of the Medical Device Amendments (the Amendments) to the Federal Food, Drug, and Cosmetic (FD&C) Act, added specific authority to the Food and Drug Administration (FDA) for the regulation of medical devices. A broad definition was given to the term "device." The amendments defined a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals; and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes."

The definition covers all such readily recognized devices as anesthesia machines and cardiac monitors and also includes devices intended for use in the diagnosis of conditions other than disease, such as pregnancy, and in vitro diagnostic products, including those previously regulated as drugs.

Some devices may be regulated by more than one law. For example, radiation-emitting medical devices must comply with the FD&C Act as amended, as well as the Radiation Control for Health and Safety Act. This interaction has been simplified by combining the former Bureaus of Medical Devices and Radiological Health to form the Center for Devices and Radiological Health (CDRH). The CDRH's Division of Compliance Operations (301-427-7304) provides guidance concerning interpretation of the FD&C Act and implementing regulations.

The FD&C Act requires the FDA to classify all de-
devices intended for human use into one of three regulatory classes. The level of classification (I, II, or III) is based upon the extent of control necessary to assure the safety and effectiveness of each device.

**Class I, “General Controls,”** regulates devices for which controls other than performance standards or premarket approval are sufficient to assure safety and effectiveness. Class I regulations (1) prohibit adulterated or misbranded devices; (2) require domestic device manufacturers and initial distributors to register their establishments and list their devices; (3) grant the FDA authority to ban certain devices; (4) provide for notification of risks and of repair, replacement, or refund; (5) restrict the sale, distribution, or use of certain devices; and (6) govern good manufacturing practices, records and reports, and inspections. These minimum requirements apply also to class II and class III devices. Some examples of class I devices are stools, trays, and nasal oxygen catheters.

**Class II, “Performance Standards,”** regulates devices for which general controls alone are insufficient to assure safety and effectiveness, but for which there is sufficient information to establish a performance standard that provides this assurance. Class II devices must comply not only with general controls, but also with an applicable standard developed under section 514 of the FD&C Act. As of March 1985, however, there are no mandatory performance standards for medical devices. Until performance standards are established by regulation, only general controls apply. The CDRH has published its intention to begin preparation of mandatory standards for the following 11 medical devices:

1. Continuous ventilators
2. Vascular graft prostheses of 6 mm and greater diameter
3. Cardiac monitors, including cardiotachometers and rate alarms
4. Ventilator tubing
5. Breathing frequency monitors
6. Central nervous system fluid shunts and components
7. Toxoplasma gondii serological reagents
8. Rheumatoid factor immunological test systems
9. Calibrators for hemoglobin or hematocrit measurement
10. Antimicrobial susceptibility test discs
11. Immunological test systems for immunoglobulins A, G, M, D, and E

As the development and promulgation of mandatory performance standards can be expected to take several years, for the present all class II devices will continue to be regulated essentially the same as class I devices.

**Class III, “Premarket Approval,”** regulates devices for which insufficient information exists to ensure that general controls and performance standards provide reasonable assurance of safety and effectiveness. Generally, class III devices are those represented as life sustaining or life supporting, those implanted in the body, or those presenting potential unreasonable risk of illness or injury. In addition, “new” devices, i.e., those that are not substantially equivalent to any device that was in commercial distribution before May 28, 1976, when the Amendments became effective, are automatically regulated as class III devices. New class III devices must have approved premarket approval (PMA) applications.

As of March 1985 only one preamendment device, the implanted cerebellar stimulator, is required to have PMA. However, the FDA plans to require, in the near future, the submission of PMA applications for the following 12 other preamendment devices:

1. Automated differential cell counters
2. Automated heparin analyzers
3. Automated blood cell separators
4. Implantable pacemaker pulse generators
5. Pacemaker programmers
6. Replacement heart valves
7. Infant radiant warmers
8. Implanted diaphragmatic/phrenic nerve stimulators
9. Implanted intracerebral/subcortical stimulators for pain relief
10. Transabdominal amnioscopes (fetoscopes) and accessories
11. Contraceptive intrauterine device and introducer
12. Contraceptive tubal occlusion devices and introducers

Until PMAs for specific preamendment class III devices are called for by regulation, these devices are subject only to general controls.

There are basically two methods for getting a device to market. The first requires that the manufacturer notify the FDA of the intent to market the device, and attempt to demonstrate that the device is substantially equivalent to devices that were in commercial distribution prior to May 28, 1976, when the Amendments became effective. This method is referred to as a premarket notification, or “510(k),” from that section of the FD&C Act that requires it. The FDA normally reaches a decision within 90 days of receiving a 510(k). If substantial equivalence cannot be established, the device is con-