Amendments of 1976 (Pub. L. 94–295, hereinafter called the amendments) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three classes of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I, general controls; class II, special controls; and class III, premarket approval.

The effect of classifying a device into class I is to require that the device meet only the general controls which are applicable to all devices. Two types of devices are classified into class I. The first type of class I device is comprised of those devices for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices (section 513(a)(1)(A)(i) of the act). The second type of class I device consists of those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device * * * but are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health and do not present a potential unreasonable risk of illness or injury (section 513(a)(1)(A)(ii) of the act). A ''potential unreasonable risk of illness or injury'' includes actual risk, as well as potential risk. Thus, the risk may be one demonstrated by reported injuries; i.e., medical device reports (MDR's), or it may simply be foreseeable. See H. Rept. 853, 94th Cong., 2d. sess. 36 (1990).

The effect of classifying a device into class II is to require the device to meet general controls as well as special controls, which together provide reasonable assurance of the safety and effectiveness of the device. Class II devices include devices which cannot be classified in class I because general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards (see section 513(a)(1)(B) of the act).

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 (PMA) that includes information concerning safety and effectiveness of the device.

II. Reclassification Criteria

Pursuant to section 513(e)(1) of the act, based on new information respecting a device, the agency may, upon its own initiative, by regulation change a device's classification and revoke, because of the change in classification, any regulation or requirement in effect with respect to such device under sections 514 or 515 of the act (21 U.S.C. 360d or 21 U.S.C. 360e). The new information respecting a device must demonstrate that either more regulatory control is needed to provide reasonable assurance of the device's safety and effectiveness or that less regulatory control is sufficient to provide such assurance. The following developments have produced new information relating to the devices which justifies reclassifying these devices.

A. The SMDA Provisions

In the **Federal Register** of September 14, 1984 (49 FR 36326 at 36348), FDA issued MDR regulations (21 CFR part 803). These regulations required manufacturers and importers of medical devices, including diagnostic devices, to report to FDA whenever the manufacturer or importer becomes aware of information that reasonably suggests that one of its marketed devices: (1) May have caused or contributed to a death or serious injury, or (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Because these MDR regulations were not always adequate to protect the public health, the SMDA, which was signed into law on November 28, 1990, added the following MDR requirements and provisions, as well as other requirements and provisions:

(1) Section 518(e) of the act (21 U.S.C. 360h(e)) allows FDA to order a manufacturer or other appropriate firm to immediately cease distribution of a device and immediately notify health professionals and device user facilities to cease using the device after FDA has determined that there is a reasonable probability that the device would cause serious adverse health consequences or death.

(2) Section 519(a)(6) of the act (21 U.S.C. 360i(a)(6)) requires distributors of medical devices to report to FDA adverse experiences related to devices, and to submit copies of reports to device manufacturers.

(3) Section 519(b)(1) of the act (21 U.S.C. 360i(b)(1)) requires certain device user facilities (hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities which are not physician's offices) to report to FDA and the manufacturer, if known, deaths related to medical devices. Additionally, under this section, device user facilities are required to report to the manufacturer, or to FDA if the manufacturer is unknown, device-related serious illnesses or injuries. User facilities are also required to submit a semiannual report to FDA summarizing the reports they have submitted. Under this section, reporting is limited to events involving a facility's patients.

(4) Section 519(d) of the act (21 U.S.C. 360e(d)) requires manufacturers, importers, and distributors to certify to FDA the number of reports submitted in a year or the fact that no such reports have been submitted to the agency.

(5) Section 519(f) of the act (21 U.S.C. 360i(f)) requires manufacturers, importers, and distributors to report to FDA any removals or corrections of a device intended to reduce a risk to health posed by a device or to remedy a violation of the act which may present a risk to health.

These new authorities, which are applicable to all devices, including class I devices, will enable FDA to monitor the 112 devices proposed for reclassification more closely and to take appropriate remedial action, if necessary.

B. The Device Priority Model

Assuring the safety and effectiveness of all medical devices is an extremely complex and difficult task in light of the number and diversity of devices being marketed. Thus, in 1989, FDA's Office of Standards and Regulations established a Device Priority Model (DPM) to help set priorities for all medical device activities (Ref. 1).

The DPM uses six general parameters, referred to as evaluation factors, to describe and calculate a priority score for each device. The six evaluation factors used in the model are: Frequency of mortality, effectiveness, health benefit, frequency of use, frequency of serious injury, and frequency of less serious injury.

The values for these evaluation factors are combined linearly using weights which represent the relative societal importance of each evaluation factor. The evaluation factors and assigned model weights are as follows: Frequency of death .38, frequency of serious injury .30, frequency of less serious injury .12, frequency of use .08, health benefit .08, and effectiveness .04.

After assigning model weights to the evaluation factors, a three level scoring scheme is applied. Predetermined