ranges of the values of the evaluation factors were used to determine a high, medium, or low scoring level. For frequency of death, frequency of serious injury, and frequency of less serious injury, the correspondence between the estimates for evaluation factor values and evaluation factor scores are: High = 100, medium = 50, and low = 0. The corresponding evaluation factor values and evaluation factor scores for the remaining three evaluation factors (frequency of use, health benefit, and effectiveness) are reversed; low = 100, medium = 50, high = 0. The reason for this reversal is as follows: If one considers two devices that are associated with an equal annual incidence of deaths and injuries, the device that should have the highest priority for FDA action is the one with the highest intrinsic risk per use, the lowest health benefit, and the lowest effectiveness.

The resulting number is called the priority score and is calculated by multiplying the score by the weight. The priority score is used to flag devices that may require more extensive analysis.

C. The Three Tier System

In early 1994, FDA's Office of Device Evaluation undertook a risk assessment of all devices in order to ensure the proper allocation of resources for the review process. Under this risk assessment, all class I, class II, and class III devices were placed into one of three tiers based upon the inherent risk associated with each device. Tier 3 devices include many first and second of a kind devices utilizing new technology or having new intended uses(s), as well as other devices determined by their inherent risk to require an intensive review. These tier 3 devices require intensive scientific and labeling review by a review team as well as advisory panel input. Most tier 3 devices require the submission of a premarket approval application. Tier 2 devices include devices which require routine scientific and labeling review. This tier encompasses the majority of 510(k)'s and select PMA's. Tier 1 devices include devices which require only a focused labeling review for intended use/indications for use and devices which have: (1) A score in the DPM less than 30 and/or; (2) no MDR death reports in any of the previous 3 years; and (3) 10 or fewer total injury reports in the previous 3 years.

III. Class II Devices To Be Reclassified Into Class I

The agency has carefully reviewed all available information concerning all class II, tier 1 devices. Based on this review, FDA is now proposing to reclassify 112 class II, tier 1 devices into class I. All of these devices were originally classified into class II under the original definition of class II devices which was defined as ''a device which cannot be classified as a class I because general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, for which there is sufficient information to establish a performance standard to provide such assurance, * * *.'' See H. Rept. 94–853, 94th Cong., 2d sess. 107 (1976). To date, no performance standards have been promulgated. Thus, any risks presented by these 112 devices have been addressed solely by general controls. The lack of adverse events or threats to the public health reported in the new information described above, supports agency's conclusion that general controls are adequate to provide reasonable assurance of safety and effectiveness for the 112 devices. In light of the new SMDA requirements, the new information gathered in response to the development of the DPM, and the three tier risk assessment system, FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of these devices.

IV. Proposed Exemptions

Section 513(d)(2)(A) of the act authorizes FDA to exempt, by regulation, a generic type of class I device from, among other things, the requirement of premarket notification in section 510(k) of the act (21 U.S.C. 360(k)). Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA. When FDA issued proposed regulations classifying preamendments devices, the agency focused on granting exemptions from the requirement of premarket notification principally when the advisory panels included them in their recommendations to the agency. Subsequently, FDA decided to exempt certain additional class I devices from the requirement of premarket notification in order to reduce the number of unnecessary premarket notifications. Moreover, in accordance with the agency's policy of reducing the number of unnecessary premarket notifications, in the **Federal Register** of December 7, 1994 (59 FR 63005), FDA exempted 148 generic types of class I devices from the requirement of premarket notification, with limitations. These actions help to free agency resources for the review of more complex notifications to FDA.

A. Description of Proposed Exemptions

In considering whether to exempt additional class I devices from premarket notification, FDA focused on whether notification for the type of device is unnecessary for the protection of the public health. For the devices in this document, FDA has concluded that premarket notification is unnecessary primarily for the following reasons:

(1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials. When making these determinations, FDA generally has considered the frequency, persistence, cause, or seriousness of such claims or risks, as well as other factors deemed relevant.

(2) In general, the following factors apply: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that could affect safety and effectiveness will either: (i) Be readily detectable by users by visual examination or other means, such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or (ii) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) any changes in the device would not be likely to result in a change in the device's classification.

For the 124 devices, FDA has made the determinations described above based on its knowledge of the devices, including past experience and relevant reports or studies on device performance. Where FDA has concerns only about certain types of changes to a particular class I device, the agency is proposing a limited exemption from premarket notification for that generic type of device. A limited exemption will specify the types of changes to the device for which manufacturers are required to submit a premarket notification. For example, for some devices FDA is proposing to exempt the device from the requirement of premarket notification except when a manufacturer intends to use a different material.

FDA advises manufacturers that an exemption from the requirement of premarket notification is not an exemption from any of the other general controls under the act, including current good manufacturing practices (CGMP's), unless explicitly stated. Indeed, FDA's decision to propose 510(k) exemptions for these devices is based, in part, on the fact that compliance with CGMP's will help ensure product quality.