- 2. Risks to health. An identification of the risks to health should be provided. This section should summarize all adverse safety and effectiveness information, which have not been submitted under section 519 of the act, particularly the most significant. The mechanisms or procedures which will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.
- 3. Recommendation. A statement whether the manufacturer believes the device should be reclassified into class I or class II.
- 4. Summary of reasons for recommendation. Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.
- 5. Summary of valid scientific evidence on which the recommendation is based. Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II).

Valid scientific evidence consists of evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, welldocumented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. (See § 860.7(c)(2).)

According to $\S 860.7(d)(1)$ there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, pursuant

to § 860.7(e)(1), there is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions. Magnetic resonance imaging devices, Docket Nos. 87P-0214/CP through 87P-0215/CP0013, and Nd:YAG Laser for posterior capsulotomy devices, Docket No. 86P-0083, were both reclassified from class III to class II subsequent to the submission of a reclassification petition. Both petitions are available upon submission of a Freedom of Information request to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20850.

IV. Submission of Required Information

The summary of, and citation to, any information required by the act must be submitted by the dates listed above to the Document Mail Center (address above).

Dated: July 13, 1995.

Joseph A. Levitt,

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Deputy Director for Regulations Policy, Center for Devices and Radiological Health. [FR Doc. 95–19945 Filed 8–11–95; 8:45 am]