

powers to deter noncompliance. Violations of section 301 of the act may be subject to seizure or injunction under sections 304(a) and 302(a) of the act (21 U.S.C. 334(a) and 332(a) respectively). In addition, violations under section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)) and criminal prosecution under section 303(a) of the act (21 U.S.C. 333(a)).

III. Order

The agency is hereby issuing this order under sections 515(i) and 519 of the act and § 860.7(g)(1) of the regulations. Under the order, the required information shall be submitted by the dates listed below so that FDA may begin promptly the process established by section 515(i) of the act to either revise or sustain the current classification of these devices.

A. Deadlines for Submission of Information

For the following 8 devices, the required information shall be submitted by August 14, 1996.

1. § 864.7250 *Erythropoietin assay.*
 2. § 864.7300 *Fibrin monomer paracoagulation test.*
 3. § 876.3630 *Penile rigidity implant.*
 4. § 878.5360 *Tweezer-type epilator.*
 5. § 884.1060 *Endometrial aspirator.*
 6. § 884.1100 *Endometrial brush.*
 7. § 884.1185 *Endometrial washer.*
 8. § 886.3920 *Eye valve implant.*
- For the following 9 devices, the required information shall be submitted by February 14, 1997.
9. § 866.3305 *Herpes simplex virus serological reagents.*
 10. § 866.3510 *Rubella virus serological reagents.*
 11. § 870.3620 *Pacemaker lead adaptor.*
 12. § 872.6080 *Airbrush.*
 13. § 876.4480 *Electrohydraulic lithotripter.*
 14. § 878.3610 *Esophageal prosthesis.*
 15. § 878.3720 *Tracheal prosthesis.*
 16. § 884.4100 *Endoscopic electrocautery and accessories.*
 17. § 884.4150 *Bipolar endoscopic coagulator-cutter and accessories.*

For the following 10 devices, the required information shall be submitted by August 14, 1997.

18. § 868.1150 *Indwelling blood carbon dioxide partial pressure (Pco2) analyzer.*
19. § 868.1170 *Indwelling blood hydrogen ion concentration (pH) analyzer.*
20. § 868.1200 *Indwelling blood oxygen partial pressure (Pco2) analyzer.*
21. § 870.3680(b) *Cardiovascular permanent pacemaker electrode.*

22. § 870.4260 *Cardiopulmonary bypass arterial line blood filter.*

23. § 870.4350 *Cardiopulmonary bypass oxygenator.*

24. § 876.5860 *High permeability hemodialysis system.*

25. § 878.5650 *Topical oxygen chamber for extremities.*

26. § 882.5940 *Electroconvulsive therapy device.*

27. § 888.3660 *Shoulder joint metal/polymer semi-constrained cemented prosthesis.*

For the following 4 devices, the required information shall be submitted by August 14, 1998.

28. § 870.3710 *Pacemaker repair or replacement material.*

29. § 870.4320 *Cardiopulmonary bypass pulsatile flow generator.*

30. § 870.5200 *External cardiac compressor.*

31. § 876.5540(b)(1) *Implanted blood access device.*

B. Required Contents of Submissions

By the dates listed above, all manufacturers currently marketing preamendments class III devices subject to this order shall provide a summary of, and citation to, any information known or otherwise available to them respecting the devices, including adverse safety and effectiveness data which has not been submitted under section 519 of the act. FDA suggests that it may be in the best interest of submitters to summarize the information submitted under section 519 of the act to facilitate FDA's decision making, even though such information is not required.

The information should be submitted in one of the two following formats depending on whether the applicant is aware of any information which would support the reclassification of the device into class I (general controls) or class II (special controls). Information which would support the reclassification of the device must consist of adequate, valid scientific evidence showing that general controls alone (class I), or general controls and special controls (class II) will provide a reasonable assurance of the safety and effectiveness of the device.

For manufacturers who do *not* believe that existing information would support the reclassification of their device into class I or class II, the information provided should be submitted in the following format:

1. *Indications for use.* A general description of the disease or condition to be diagnosed, treated, cured, mitigated, or prevented, including a description of the patient population for which the device is intended.

2. *Device description.* An explanation of how the device functions, significant physical and performance characteristics of the device, and basic scientific concepts that form the basis for the device.

3. *Other device labeling.* Other device labeling that includes contraindications, warnings and precautions and/or promotional materials.

4. *Risks.* A summary of all adverse safety and effectiveness information and identification of the risks presented by the device as well as any mechanisms or procedures which will control the risk.

5. *Alternative practices and procedures.* A description of alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

6. *Summary of preclinical and clinical data.* The summary of preclinical and clinical data should include the conclusions drawn from the studies which support the safety and effectiveness of the device as well as special controls, if any, which address the adverse effects of the device on health. The summary should include a brief description of the objective of the studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive. The summary of the clinical study(ies) should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

7. *Bibliography.* A copy of the key references, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness evaluation of the device.

Manufacturers who believe that existing information would support the reclassification of their device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition, which should include the information described below in addition to the information required under 21 CFR 860.123.

1. *Identification.* A brief narrative identification of the device. This identification should be specific enough to distinguish a particular device from a generic type of device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.