

testing, and labeling recommendations for the devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the special control guidance.

Following the effective date of this final rule, any firm submitting a 510(k) premarket notification for a new surgical suture will need to address the recommendations in the special control guidance. However, the firm need only show that its device is as safe and effective as a device that meets guidance recommendations. The firm may use alternative approaches if those approaches address the performance, testing, and labeling issues identified in the guidance.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The special controls guidance document does not impose any new burdens on manufacturers of these devices. FDA has granted 201 substantial equivalence orders from 95 manufacturers of these devices in the last 10 years. The guidance document is based upon the review of the information submitted in these premarket notifications. Based on the review of the premarket notifications, FDA believes that manufacturers

presently marketing these devices are in conformance with the guidance document and they will not need to take any further action. The guidance document merely assures that, in the future, devices of these generic types will be at least as safe and effective as the presently marketed devices. These devices are already subject to premarket notification and labeling requirements. The guidance document advises manufacturers on appropriate means of complying with these requirements.

The consensus standards in the guidance were recognized under section 514(c) of the act (21 U.S.C. 360d(c)) for the purpose of demonstrating certain aspects of substantial equivalency. The manufacturer may provide a declaration of conformity to a recognized standard to meet a premarket notification requirement. Ordinarily, this will provide a simplified method of meeting the requirement. The manufacturer may choose to submit other data or information to meet the requirement. The guidance document sets out options that the manufacturer has in this respect.

For the foregoing reasons, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

List of Subjects in 21 CFR Part 878

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Section 878.4493 is amended by revising paragraph (b) to read as follows:

§ 878.4493 Absorbable poly(glycolide/L-lactide) surgical suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

■ 3. Section 878.4495 is amended by revising paragraph (b) to read as follows:

§ 878.4495 Stainless steel suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

■ 4. Section 878.4830 is amended by revising paragraph (b) to read as follows:

§ 878.4830 Absorbable surgical gut suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

■ 5. Section 878.5000 is amended by revising paragraph (b) to read as follows:

§ 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture.

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(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

■ 6. Section 878.5010 is amended by revising paragraph (b) to read as follows: