

provides that, upon receipt of a "not substantially equivalent" determination, a 510(k) applicant may request FDA to classify a postamendments device into class I or class II. Within 60 days from the date of such a written request, FDA must classify the device by written order. If FDA classifies the device into class I or II, the applicant has then received clearance to market the device and it can be used as a predicate device for other 510(k)s. It is expected that this process will be used for low risk devices. This process does not apply to devices that have been classified by regulation into class III, i.e., preamendments class III devices, or class III devices for which a PMA is appropriate.

Under section 513(f)(3)(B)(i) of the act, formerly section 513(f)(2)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device classification panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Recommendation of the Panel

On July 2, 1997, FDA filed the reclassification petition submitted by BioMerieux Vitek, Inc., requesting reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility devices from class III to class II. FDA consulted with the Microbiology Devices Panel (the panel). During an open public meeting on February 13, 1998, the panel unanimously recommended that FDA reclassify the fully automated short-term incubation cycle antimicrobial susceptibility device for use in determining in vitro susceptibility of bacterial pathogens isolated from clinical specimens from class III to class II. The panel identified the risks to health regarding use of this device as the reporting of erroneous results, citing that insufficient testing of each unique antimicrobial agent with an inappropriate clinical and challenge organism, the use of an uncalibrated inoculum, or a nonstandardized acceptable error endpoint can result in such erroneous reports.

FDA considered the panel's recommendations and tentatively agreed that the generic type of device, the fully automated short-term incubation cycle antimicrobial susceptibility device for

use in determining in vitro susceptibility of bacterial pathogens isolated from clinical specimens, be reclassified from class III to class II. Subsequently, in the **Federal Register** of March 8, 2000 (65 FR 12268), FDA issued a notice of the panel's recommendation for public comment.

After reviewing the information in the petition and presenting it before the panel, and after considering the panel's recommendation and the comments received in response to the notice of panel recommendation, FDA issued an order to the petitioner on December 28, 2001, reclassifying the fully automated short-term incubation cycle antimicrobial susceptibility device and substantially equivalent devices of this generic type, from class III to class II with the implementation of special controls. The special control applicable to this generic type of device is a guidance document entitled "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA." FDA has identified the administration of an inappropriate antimicrobial agent to the patient as the risk to health associated with use of this device. The guidance document contains sections that discuss the use of appropriate challenge strains; standardized preparation of inoculum; the application of "acceptable error" as a range with confidence intervals; and appropriate clinical performance testing. In this way, the guidance will minimize the sources of erroneous reporting associated with the fully automated short-term incubation cycle antimicrobial susceptibility device. Testing and labeling recommendations are also discussed in the guidance document and also help manufacturers address the risk to health. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a fully automated short-term incubation cycle antimicrobial susceptibility device will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Accordingly, as required by § 860.134(b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of the fully automated short-term incubation cycle antimicrobial susceptibility device from class III into class II. FDA is codifying the reclassification and the special control guidance by adding new § 866.1645. For the convenience of the

reader, FDA is also adding a new § 866.1(e) to inform the reader where to find guidance documents referenced in 21 CFR part 866.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this reclassification 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.

IV. Analysis of Impacts

FDA has examined the impacts of the notice 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 final 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. Reclassification of the device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore 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 \$110 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis pursuant to section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth