

goes beyond a simple display of raw data should provide clinical information and verification that the information provided by these devices has clinical and diagnostic validity, sensitivity, and specificity and, therefore, the special control, in addition to the general controls, is necessary to provide reasonable assurance of safety and effectiveness.

III. Summary of Final Rule

FDA concurs that the dental sonography device and the jaw tracking device, used to monitor temporomandibular joint sounds and mandibular jaw positions relative to the maxilla, respectively, should be classified into class I (general controls). General controls would provide reasonable assurance of safety and effectiveness for these devices for these intended uses. FDA, however, believes that the dental sonography device and the jaw tracking device used to interpret temporomandibular joint sounds and mandibular jaw positions relative to the maxilla, respectively, for the diagnosis of temporomandibular joint disorders and associated orofacial pain should be classified into class II (special controls). Premarket notification for dental sonography and jaw tracking devices with these intended uses should include clinical information to demonstrate performance, as well as labeling instructing the user on proper technique, interpretation of the device outputs, and appropriate warnings and precautions. FDA concurs with the Panel's recommendation that these devices should be subject to sale by or on the order of a licensed practitioner.

FDA disagrees with the Panel that the class I devices should require premarket notification because they meet the reserved criteria of section 510(l) of the act. FDA believes that the intended uses of monitoring sounds emanated from the temporomandibular joint or monitoring mandibular jaw positions relative to the maxilla should be exempt from premarket notification. FDA believes these devices for these intended uses are not of substantial importance in preventing impairment of human health, nor do they present an unreasonable risk of illness or injury.

FDA, however, is classifying into class II, the dental sonography device and the jaw tracking device used to interpret temporomandibular joint sounds and mandibular jaw positions relative to the maxilla, respectively, for the diagnosis of temporomandibular joint disorders and associated orofacial pain. Section 510(m) of the act provides that a class II device may be exempted from the premarket notification

requirements, if FDA determines that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness. FDA concludes that premarket notification is necessary.

FDA has identified the following risks to health associated with the class II devices as follows: (1) *Electrical interference*. Electrical interference generated by these devices may affect diagnostic and therapeutic medical devices, such as certain types of cardiac pacemakers; (2) *Improper treatment*. There is no general consensus or established standard of care regarding the interpretation of the output of these devices. Therefore, a misdiagnosis of temporomandibular joint disorders and associated orofacial pain may lead to improper treatment.

IV. Special Controls Guidance Document

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices." This guidance document will serve as the special control for the class II dental sonography and jaw tracking devices.

FDA believes that review of performance characteristics described in the special controls guidance and appropriate labeling can ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device must submit to FDA a premarket notification submission before marketing the device. Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for these class II devices 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.

V. Environmental Impact

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

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C.

601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives. If regulation is necessary, a regulatory agency must plot a course that maximizes net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. Additionally, as defined by the Executive order the final rule does not constitute a significant regulatory action. As a result, the final rule 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 class I devices are already subject to the general controls provisions of the act. The special controls guidance does not impose any new requirements on manufacturers of class I devices. Manufacturers of the class II dental sonography and jaw tracking devices currently are required to submit premarket notifications. The guidance document reflects existing FDA practice in the review of these premarket notifications. FDA expects that manufacturers of cleared dental sonography and jaw tracking devices will not have to take any additional action in response to this rule. This rule will help expedite the review process for any new manufacturers of these devices. The agency therefore certifies that the final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final 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 of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. 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