

SEC. 522. [21 USC §360I] Postmarket Surveillance

1 (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

(1) implanted in the human body for more than one year, or

(2) a life sustaining or life supporting device used outside a device user facility.

(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562.

Footnote

1. Section 212 of Public Law 107–250 (116 Stat. 1614), as amended by section 2(d)(3)(C) of Public Law 108–214 (118 Stat. 577), provides for a study whose purpose is determining whether the system under the Federal Food, Drug, and Cosmetic Act for the postmarket surveillance of medical devices provides adequate safeguards regarding the use of devices in pediatric populations. The study is required to be submitted not later than four years after the date of the enactment of Public Law 107–250, which was enacted October 26, 2002.