

FDA Fact Sheets: Postmarket Surveillance

FDA has a range of requirements that can be imposed on manufacturers regarding postmarket surveillance activities.

Postmarket surveillance is defined as the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device that may be used to reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health and safety. This requirement may be imposed on any Class II or Class III medical device which: 1) would cause serious adverse health consequences with a reasonable likelihood if the device were to fail; 2) is intended to be implanted into the human body for more than one year; or 3) is intended to be used to support or sustain life and will be used outside of a user facility. Procedures and requirements for postmarket surveillance are outlined in 21 CFR 822.

Those devices requiring postmarket surveillance are identified by an FDA postmarket surveillance order, which notifies the device manufacturer of the requirement to conduct postmarket surveillance. Prior to dispatching the postmarket surveillance order, or as part of the order, FDA will specify the devices subject to the order and the reason for the required surveillance. In addition, FDA will provide the manufacturer any general or specific guidance available to assist in the development of a postmarket surveillance plan. The manufacturer's postmarket surveillance plan must be submitted to FDA within 30 days from receipt of the postmarket surveillance order.