# FDA Fact Sheets:
# Medical Device Reporting

Post-marketing surveillance of adverse events involving medical devices is the responsibility of both the device manufacturer and the health care facility utilizing the device. Medical Device Reporting (MDR) regulations require manufacturers to report to FDA device-related incidents, deaths, serious injuries, and device malfunctions which are likely to cause or contribute to death or serious injury if they were to occur. Health care facilities are required to report patient deaths suspected of being associated with devices to both the manufacturer and FDA. Users are only required to report serious injuries to the manufacturer (or to FDA if the manufacturer is not known). The following definitions identify reportable events:

- **Serious Injury**: Life threatening injuries; injuries that result in permanent damage or impairment; and injuries that require medical intervention to preclude permanent damage or impairment.
- **Malfunction**: The failure of a device to meet its performance specifications or to perform as intended. A malfunction is considered to be a reportable event when it is likely to cause or contribute to a death or serious injury if it were to occur. By definition, a malfunction does not involve a patient injury.

Manufacturers are required to report a device-related death, serious injury, or malfunction to FDA within 30 days of becoming aware of the event, or within five work days if there is an unreasonable risk of substantial harm to the public health or when required by FDA for specific devices or types of events. A user facility is required to submit notification of a medical device causing or contributing to a death or serious injury within 10 work days from the time that the situation has become known to the facility. The following two postmarket surveillance systems are currently used to monitor adverse event reports:

- **Medical Device Reporting (MDR)**: The MDR system is used to monitor device-related adverse events, including deaths, serious injuries, and device malfunctions. The system is intended to provide FDA with significant medical device adverse event information from manufacturers, importers, and user facilities.
- **MedWatch**: MedWatch is the process by which both mandatory and voluntary adverse events are reported. Health care facilities use the MedWatch form to report events. Health care practitioners and patients may also use the form to voluntarily report adverse events.

Medical device reports are maintained in the Manufacturer and User Facility Device Experience (MAUDE) database, which consists of voluntary, user facility, distributor, and manufacturer reports, and the MDR Database.