

FDA Fact Sheets: Medical Device Tracking

FDA has the authority to order manufacturers of certain medical devices to establish and maintain systems to track their devices (21 CFR 821). This is to ensure manufacturers can expeditiously remove a device from the market if necessary and notify patients and providers of any significant issues with a device.

Medical device tracking is required for devices whose failure would be reasonably likely to have serious and adverse health consequences; are intended to be implanted in the human body for more than one year; or are life-sustaining or life-supporting devices that are used outside of a device user facility.