

List of Tracked Devices

This list is current as of October 2007:

IMPLANTABLE DEVICES

- Temporomandibular joint (TMJ) prosthesis
- Glenoid fossa prosthesis
- Mandibular condyle prosthesis
- Implantable pacemaker pulse generator
- Cardiovascular permanent implantable pacemaker electrode
- Replacement heart valve (mechanical only)
- Automatic implantable cardioverter-defibrillator
- Implanted cerebellar stimulator
- Implanted diaphragmatic/phrenic nerve stimulator
- Implantable infusion pumps
- Abdominal aortic aneurysm stent grafts
- Silicone gel-filled breast implants
- Cultured epidermal autografts

DEVICES USED OUTSIDE A DEVICE USER FACILITY

- Ventricular bypass (assist) devices
- Breathing-frequency monitors (apnea monitors)
- Continuous ventilators
- Direct-current (DC) defibrillators and paddles

Source: U.S. Food and Drug Administration. Center for Devices and Radiological Health. Medical device tracking. Guidance for industry and FDA staff [online]. 2007 Oct 25 [cited 2007 Oct 26]. Available from Internet: <http://www.fda.gov/cdrh/comp/guidance/169.html>. ■

Tracking Timeline

August 1998. Tracking orders were repealed for the following devices: intraocular lenses, vascular graft prostheses, interarticular disc prostheses (interpositional implant), annuloplasty rings, tracheal prostheses, arterial stents (used in coronary or peripheral arteries), penile inflatable implants, silicone inflatable breast prostheses, silicone gel-filled breast prostheses, silicone gel-filled testicular prostheses, silicone gel-filled chin prostheses, silicone gel-filled Angelchik reflux valves, and infusion pumps (not electromechanical or used outside a user facility).

May 2003. Electromechanical infusion pumps were repealed from the list.

May 2005. FDA transferred oversight of dura mater from the Center for Devices and Radiological Health to the Center for Biologics Evaluation and Research. The transfer was effective on May 25, 2005, when FDA's good tissue practice regulations went into effect. The regulations, which establish tracking and reporting requirements for establishments that manufacture human cell, tissue, and cellular- and tissue-based products, define human dura mater as tissue (21 CFR § 1271.3[d]). Previously, dura mater was considered a device subject to the medical device tracking requirements. Once it was redefined as tissue, dura mater became subject to the tissue tracking requirements instead.

November 2006. FDA added silicone gel-filled breast implants back on the list of tracked devices.

October 2007. FDA added cultured epidermal autografts to the list of tracked devices ■