Term	Meaning (As defined by the FDA official website)
Adulteration	A device is held to be adulterated if it includes any filthy, putrid, or decomposed substance, or if it is prepared, packed, or held under unsanitary conditions. Furthermore, a device is held to be adulterated if: - Its container is composed, in whole or part, of any poisonous or deleterious substance; - It contains, for the purposes of coloring only, an unsafe color additive; and - Its strength differs from, or its purity or quality falls below, that which it claims to represent.
Misbranding	A drug or device is deemed to be misbranded if: - Its labeling is false and misleading. - Its packaging does not bear a label containing: 1) the name of the place of business of the manufacturer, packer, or distributor, and 2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count. - Its label does not bear adequate directions for use. The label must include warnings against use in certain pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application.
Device Listing Requirements	MD manufacturers must submit to the FDA a list of all devices they produce or process. This listing is maintained by the FDA.
Premarket Notification	A manufacturer who intends to market a medical device must submit a premarket notification [510(k)] to the Agency at least 90 days before introducing the device onto the market. The 510(k) premarket submission demonstrates that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device.
Banned Devices	If the Agency determines, on the basis of all available data and information, that a device intended for human use presents deception or risk of illness or injury, which cannot be corrected by a change in the labeling, then the Agency may publish a proposed regulation to ban the device in the Federal Register.
Restricted devices	A restricted device can only be sold on oral or written authorization by a licensed practitioner or under conditions specified by regulation. Devices such as cardiac pacemakers and heart valves, for example, require a practitioner's authorization. Hearing aids are restricted by a regulation which limits their sale to persons who have obtained a medical evaluation of their hearing loss by a physician within six months prior to the sale of the hearing aid.
GMP	Manufacturing, packing, storage, and installation of devices must conform to current good manufacturing practices (GMPs).