

After completion of the registration process, all devices to be sold within the U.S. must be listed. Listing involves completing form FD2892. All devices exported to the U.S. must be listed by generic category with the FDA. Only one form is required for each generic category. The listing data must be updated when a new device is marketed with a different classification name, the intended use changes, a product is discontinued, a discontinued product is re-marketed, or any information on the FD2892 form changes.

After a company is registered and its medical devices listed, the next step is "pre-market notification." The FDA must be notified 90 days prior to the distribution of medical devices (form 510(k)).

The most stringent process of medical device review is "pre-market approval." The process is lengthy and complex, with the review time for medical devices often taking 180 days.

Good Manufacturing Practices (GMP) is a quality assurance program mandated by the federal government. It is similar to ISO 9000 but stricter with regard to after-market sales monitoring. GMP was enacted to provide safe medical devices to the final consumer. The FDA inspects the operations and records of foreign manufacturers to determine GMP compliance. Before inspecting a Canadian firm, the FDA must receive permission from both the country and manufacturing facility.

The Division of Small Manufacturers Assistance (DSMA) within the FDA can help Canadian manufacturers with requirements related to their medical device products. Free regulatory workshops and conferences for small manufacturers are held at convenient sites in the U.S. These meetings provide an overview of the regulatory requirements for commercial distribution of medical devices in the U.S.

Imports regulated by the FDA are subject to inspection at the time of entry through U.S. customs. Shipments not in compliance will be detained. They must then be brought into compliance, destroyed or re-exported.

It is strongly recommended that Canadian companies protect every device sold in the U.S. with a "utility patent." The lifespan of the patent is 17 years, and all fees must be paid for that patent before it is valid. Once issued, a patent is legally recognized throughout the U.S., including its territories.