

OUR PRACTICE

Medical Devices

In the highly regulated medical device industry, it is critical for companies to have trusted legal counsel who know how to assist them in implementing their business strategies creatively and in compliance with all rules and regulations.

Baker Donelson is the go-to firm in our geographic footprint for emerging medical device manufacturers that need the expertise of a regulatory and quality executive but have not yet identified a candidate to fill that role in-house. In fact, we have served as regulatory and quality counsel for a wide range of medical device companies, from durable medical equipment resellers to those providing implants. One common denominator is our ability to convert business objectives into actionable regulatory plans, with an eye on key quality considerations. We have both designed and audited quality systems for clients, and we routinely guide clients through the product approval process in the U.S., Canada and Europe.

The medical device practice at Baker Donelson is unique in that it includes experience rarely found in a law firm. Many of our attorneys have served as executives of medical device companies at some point during their careers. We have also worked directly with design engineers to document the design and development process, and we have helped navigate civil penalty proceedings resulting from the device manufacturers' post-market activities, as well as many of the processes in between. Our attorneys have significant experience in guiding our clients through the various steps in the product lifecycle.

Design and Development

We have been engaged to participate in the design phase of new product launches as a means of ensuring that product design controls are implemented at the most appropriate point. We have assisted in the design and implementation of quality management systems for companies that are compliant with the FDA Quality System Regulations, ISO 13485, European Medical Device Directives, the Canadian Medical Devices Conformity Assessment System and the Japanese Ministry of Health, Labour and Welfare.

Pre-Market Clearance

Baker Donelson attorneys have worked with clients to develop strategies to bring medical devices to market, which includes pre-submission advocacy with FDA officials concerning product classification or reclassification, as well as submitting Investigational Device Exemption (IDE) applications, Premarket Approval Applications (PMA) and Premarket Notifications (510K) on behalf of clients. We also assist clients to comply with medical device listing, establishment registration, and advertising and promotion requirements.

Post-Market Surveillance

We have been very active in helping companies implement robust post-market compliance programs that ensure appropriate and timely compliance with Medical Device Reporting (MDR) requirements. We have also assisted in managing risks associated with FDA inspections and FDA enforcement actions.

The areas where Baker Donelson has experience include:

- Assisting clients in the development of self-audit, external audit and pre-inspection audit strategies.

- Assisting with the drafting of responses and formulating action plans subsequent to Form FDA 483 observations in order to avoid the further complications of a Warning Letter.
- Advising companies on how to properly conduct product recalls and other field actions.
- Having worked with the key Unique Device Identification (UDI) vendors, helping ensure that companies are compliant with their Global Unique Device Identification Database (GUDID) obligations.
- Assisting clients on a wide range of medical device import and export issues.
- Advising clients on regulatory enhancement strategies, including internal and external audits, contractual arrangements with suppliers and staff training on quality regulations.

Squarely within Baker Donelson's geographical footprint is one of the fastest growing concentration of medical device businesses in the world.* We have successfully represented many of these companies since their start-up phase.

**According to a 2014 Battelle (research and development organization) report, the growth in Georgia, Florida, South Carolina, and North Carolina is explosive. Between 2007 and 2014, the number of medical device companies has grown in these states by 64%, 48%, 40%, and 37% respectively, compared to the national average of 12%. In addition, the large medical device manufacturers are expanding operations in the region to take advantage of lower cost of living and great quality of life. Tennessee's employment in medical devices grew by nearly 20 percent. Moreover, more than 16 percent of the more than \$35 billion U.S. medical device manufacturing industry is located in the Southeast.*