wiley

Medical Devices

With technological innovation profoundly reshaping the medical device field, Wiley's decades of legal, regulatory, and policy experience – combined with our seamless collaboration across numerous areas of law – give our clients a unique competitive advantage at every stage of the product lifecycle.

We assist companies worldwide in all aspects of the medical device supply chain, providing comprehensive counsel on issues that arise long before products head to market, as well as market-entry matters and postmarket support and guidance.

Whether a client is developing a novel technology; seeking to market a new device; maneuvering to outsell a new or established competitor; or responding to a potential regulatory, legal, or enforcement action, Wiley is unmatched in navigating challenges facing the medical device industry.

Drawing on our multidisciplinary expertise – and our long-held relationships with key government decision-makers – we conduct due diligence, review transactions, and help clients drive innovations in the medical device arena that defy conventional regulatory classifications. For example, artificial intelligence and machine learning are giving medical devices a degree of autonomy that was inconceivable only a few years ago. Cloud-connected technologies are compiling health data on millions of patients and consumers, raising new privacy challenges for the U.S. Food and Drug Administration (FDA) and blurring the lines between digital health, telecommunications, privacy, cybersecurity, and other areas.

Speaking the languages of both the regulators and the medical, scientific, and technological innovators, we develop creative, cutting-edge approaches to challenges that the device industry has never confronted before. We are at the forefront of new and emerging life-sciences regulatory issues involving mobile medical apps, software as a medical device (SaMD), home diagnostic tests, telehealth, wearable devices, and a wide range of other health technologies.

To maximize our agility, efficiency, and cost-effectiveness for clients, we collaborate with Wiley colleagues in other practices including Corporate; FTC Regulation; Government Contracts; Intellectual Property; Litigation; Privacy, Cyber & Data Governance; Public Policy; Telecom, Media & Technology; and White Collar Defense & Government Investigations.

This versatility enables us to provide comprehensive legal representation in a wide range of areas, including:

- **Premarket Compliance** – We help small and global companies navigate through the FDA Center for Devices and Radiological Health's (CDRH) ever-changing policies. We assist when companies intend to bring new devices to market or reconfigure current devices to determine product classifications. Our team has experience working through informal and formal pathways with the FDA in determining device classifications (e.g., 513(g) submissions) and challenging FDA decisions on device classifications.
- **Market Entry** – We assist with Section 510(k) premarket notifications, *de novo* classification requests, IDE submissions, and humanitarian device exemption (HDE) submissions. Our medical device team also assists with disputes that may arise with the FDA during a premarket submission – working with clients and the agency toward resolution.
- **Postmarket Compliance** – Postmarket compliance requirements can be extensive, and we assist clients in many areas to minimize FDA exposure and maximize marketing potential, including:
  - Establishment registration, device listing, and user fees;
  - Medical Device Reporting (MDRs);
  - Corrections, removals, and recalls;
  - Product enhancement reportability;
  - Labels, labeling, advertising, and promotion;
  - Enforcement provisions, including inspections, warning letters, untitled letters, regulatory meetings, and administrative detentions; and
  - Import/export of devices.

At every stage in the medical device process – including the proof of concept/design phase, FDA submissions and applications, and postmarket compliance and competition matters – Wiley has the relationships, knowledge, and experience our clients have come to rely on.

Contacts

Ann M. Begley
202.719.4585 | abegley@wiley.law