Hogan Lovells

Medical Device Law

Bringing a medical device to market involves addressing a host of issues: regulatory approval, patents, financing, manufacturing, distribution, and more. After your product debuts, the challenges continue throughout its life cycle, from running compliance programs to responding to enforcement actions. And if you're operating globally, the last thing you want to do is to oversee a patchwork of different firms in different locations.

That's where Hogan Lovells comes in. We operate on a global scale, coordinating among lawyers in offices in all of the world's major medical markets to sequence and streamline regulatory approvals. In the U.S., we've been helping companies get new products approved by the Food and Drug Administration (FDA) since the Medical Device Amendments of 1976 was signed into law.

We understand how to do things in a better way to expedite the FDA approval process, streamline how much data is needed for approval to be granted, and design programs to successfully launch products and ensure continuing compliance. We can also help you develop reimbursement strategies and build the necessary infrastructure for a transaction or initial public offering.

We are unique in achieving all this because of our interdisciplinary team. Many of our lawyers have worked for regulatory agencies and in private industry, and have backgrounds in biostatistics, medicine, biomedical engineering, material science, and genetics, among other

Key contacts

Janice M. Hogan,
Philadelphia

Jonathan S. Kahan,
Washington, D.C.

Areas of focus

Adverse Event Reporting
Vigilance Reporting

Advertising and Promotion Compliance

Advisory Panel Preparation

Clinical Trials

Combination Products, FDA Jurisdictional Issues, FDA Postmarket Compliance Issues

In Vitro Diagnostics

Premarket Review

Unique Device Identifiers

disciplines. This means we understand the technology and can make better arguments on your behalf. From inception and approval to debut and product maturity, we provide guidance that takes into account the complex considerations where business and compliance meet.

Awards and rankings

- Band 1 for Healthcare: Pharmaceutical/Medical Products Regulatory in the District of Columbia, *Chambers USA*, 2018
- Highly Recommended for FDA Medical Devices, *LMG Life Sciences*, 2017
- Ranked second tier for health care and life sciences in the U.S., *Legal 500*, 2017
- Band 1 for Life Sciences, *Chambers Global*, 2018
- Band 1 for Life Sciences, *Chambers Europe*, 2017

Latest thinking and events

Sponsorships and Speaking Engagements

Master Class: Medical Device Clinical Research: The Path From Concept to Approval (Part 2)

Hogan Lovells Publications

Proposed changes to FDA guidance for the content of premarket submissions for management of cybersecurity in medical devices: What you should know
Medical Device Alert

Sponsorships and Speaking Engagements

510(k) Submissions Workshop – Fall 2018

Hogan Lovells Publications

New draft guidance proposes a shift in how the FDA will evaluate certain device modifications
Medical Device Alert

Published Works

Medical device crowdfunding and preapproval promotion: Where does FDA draw the line?
Food and Drug Law Institute

Blog Post

UK MHRA consults on no-deal Brexit legislation