Hogan Lovells

Medical Device and Technology Regulatory

Bringing a medical device to market involves addressing a host of issues: from financing and patents, to regulatory approval, 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.

Hogan Lovells has you covered. 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 your regulators and the changing regulatory landscape. This means we can help to expedite FDA approval and CE marking and design programs to successfully launch products around the world, while ensuring continuing compliance. We can also help develop reimbursement strategies to ensure your hard work leads to business success, and we can build the necessary infrastructure for a transaction or initial public offering, when the time comes.

Key contacts

Randy J. Prebula,
Washington, D.C.

Janice M. Hogan,
Philadelphia

Jonathan S. Kahan,
Washington, D.C.

Michael S. Heyl,
Washington, D.C.

Jodi Scott,
Denver

Trending Topics

Total Product Life Cycle

Hogan Lovells has you covered during the total life cycle of a Medical Device.
We have been there before. We know the rules. We know the regulators.

Life Sciences and Health Care Horizons 2022

Podcast: Talking The Cure

Unlike our competitors, we have a dedicated team of over 30 medical device experts, many of whom have worked for regulatory agencies and in private industry, and have backgrounds in biostatistics, medicine, biomedical engineering, material science, pharmacy and genetics, among other 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.

Representative experience

Assisting multiple clients regarding EUA submissions for COVID-19 diagnostic tests, treatments, and surgical masks.

Advising numerous non-traditional life sciences and device companies on the requirements and logistics of producing critical need supplies.

Advised Vayu Global Health Innovations in obtaining an EUA from FDA that allowed its bubble CPAP device to be immediately distributed to hospitals to help alleviate the ventilator shortage due to COVID-19.

Teamed up with regulatory consultant Wanda Henry Co. to advise Sansure Biotech, Inc. in its FDA EUA for a molecular diagnostic test kit for COVID-19.

Advising Ford Motor Company in its collaboration with GE Healthcare to help reinforce the Strategic National Stockpile and to support the treatment of coronavirus patients.

Advised the Kraft Group/New England Patriots to obtain the necessary government approvals to pick up 1.3 million N95 masks from Shenzhen, China, and deliver them to the Commonwealth of Massachusetts.

Developed an innovative strategy for interacting with FDA for Viz.ai to gain a quick De Novo clearance for a novel Computer-Aided Triage and Notification Platform

Areas of focus

Postmarket Compliance and Enforcement Actions

Advertising and Promotion Compliance

In Vitro Diagnostics

Premarket Review

Advisory Panel Preparation

Medical Device Artificial Intelligence

Unique Device Identifiers

State Medical Device Distribution & Manufacturer Licensing

to identify LVO strokes in CTA imaging.

Successfully assisted IDx LLC to achieve De Novo reclassification from the FDA for the ground-breaking AI-based device IDx-DR, which autonomously analyzes images of the retina for signs of diabetic retinopathy.

Assisted a client in developing a recall strategy that involved all products produced by the company, which was classified as a Class I recall.

Help develop clinical and regulatory strategies for a number of clients that are developing biomarkers and molecular diagnostics that would be companion assays to drugs.

Conducted numerous Quality System Regulation (QSR and ISO 1345) audits domestically and internationally to help companies make their processes more robust and to prepare them for inspections and audits.

Advocated the FDA's reclassification of a novel imaging device, tissue culture media products for ex vivo growth of human cells, and a variety of in vitro diagnostic test systems, avoiding the need for a PMA approval.

Assisted CSD Labs in obtaining 510(k) clearance of eMurmur, an innovative, AI-based murmur detection software.

Conducted internal investigations and compliance audits to ensure that promotional activities did not violate the Federal Food, Drug, and Cosmetic Act.

Assisted clients with novel devices featuring AI and machine learning algorithms in developing and gaining FDA alignment on creative regulatory strategies to bring these products to market quickly and efficiently.

Worked on pre-market submissions for IVDs in the medical device and biologics areas and on IND applications for imaging agents.

Assisting several medical devices clients in preparing distribution, importer, and authorized representative agreements reflecting the obligations of the EU MDR.

Awards and rankings

- Band 1 for Healthcare and Healthcare: Pharmaceuticals/ Medical Products - District of Columbia, *Chambers USA*, 2022
- Band 1 for Life Sciences, *Chambers Global: Multi-Jurisdictional*, 2022
- Band 1 for Life Sciences, *Europe-wide Chambers Europe*, 2022
- Band 1 for Life Sciences in Japan, *Chambers Asia-Pacific*, 2022
- Band 1 for Life Sciences: Regulatory/Compliance, *Chamber USA*, 2022
- Tier 2 for Healthcare: Life Sciences, *The Legal 500*, 2022
- Ranked Tier 1 for EU Regulatory: Pharmaceuticals, Medical Devices, and Biotech in Belgium, *The Legal 500*, 2022

Latest thinking and events

News

First patch to the privacy laws in Australia: increased penalties for global companies

Insights and Analysis

Key issues for vertical agreements in the life sciences sector

News

New FDA pilot offers expedited drug program sponsors expanded FDA meeting opportunities on manufacturing issues

News

FDA invites comments on Expanded Access to Investigational Drugs guidance

News

Seeking harmony: FDA to align its human subject research regulations with Common Rule

News

Spotlight on Greater China: out-licensing to Chinese counterparties