Hogan Lovells

Medical Devices

Creating and commercializing a cutting-edge medical device is demanding work. Remaining compliant in the face of ever-increasing regulation makes that job even more difficult.

We leverage the vast experience gleaned from guiding companies of all sizes through the hard-to-navigate health care environment. We ask the right questions and explore uncovered possibilities to put your product in the best position for success.

Our team of medical device lawyers, scientists, and regulatory specialists arm you with the knowledge and security you need to address each issue that occurs in regulatory clearance or approval, post-market enforcement, patents, financing, manufacturing, distribution, and more.

Representative experience

Obtaining the FDA's designation of expedited review status for a novel orthopedic and women's health device and negotiated favorable review timetables.

Instrumental in shepherding the development, clinical study, and review to achieve FDA approval of a novel synthetic cartilage implant to treat osteoarthritis in the great toe.

Conducting due diligence for investment bank on medical device startup, uncovering several important FDA issues that substantially altered the target's valuation.

Advising a U.S.-based national trade association that provides educational assistance to medical technology companies in

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Practices

Health Law

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Chinese medical device reimbursement rules and policies.

Coordinating the defense of a manufacturer of implantable class III medical devices against alleged liability in clinical trials after a voluntary worldwide product withdrawal.

Assisting a medical device manufacturer with investigations by the authorities, criminal investigations, and civil proceedings arising out of the over-exposure of patients to radiations.

Representing a leading medical device manufacturer in a global recall of one of its products in more than 70 countries.

Instrumental in the initial PMA approval for the first ever device to treat glioblastoma multiforme, and in the subsequent PMA approval to expand the indication of this technology to a broader patient population.

Assisting a client in obtaining the first waiver from the FDA under the Clinical Laboratory Improvement Amendments (CLIA) for a syphilis screening test.

Helping a major device company draft a comprehensive set of Standard Operating Procedures (SOPs) and developing a program to train regulatory personnel in these SOPs.

Defending a company during a federal criminal investigation of alleged violations, and during the client's ensuing negotiations of a criminal plea and civil settlement agreement with the DOJ and HHS'.

Developing policies and procedures to help clients come into compliance with federal and state clinical trial disclosure requirements.

Advising a medical device client on its European patent strategy relating to the launch of its adrenaline autoinjector product, including proceedings in the EPO and UK courts relating to a competitor's patent.

Advising in a global patent litigation strategy in relation to patents for medical imaging.

A medical device client was about to launch an IPO when it received an FDA Warning Letter. We evaluated the significance

and helped draft disclosures to ensure compliance with SEC requirements.

Assisting a company to reverse Medicare's national noncoverage decision and secure reimbursement by obtaining an "inpatient new technology add-on" and a Medicare Severity Diagnosis Related Group reclassification.

Representing a trade association for medical device manufacturers for over the last 12 years on coding, coverage, reimbursement issues; the medical device tax; and other legislative and policy issues.

Latest thinking and events

Published Works

Bad News for Device Sponsors: Panel Meetings were Already Going the Way of the Homework Assignment, and COVID Might "Put the Nail in the Coffin"
Food and Drug Law Institute

Published Works

Implications of the one-year postponement of the application of the Medical Devices Regulation (MDR)
LexisNexis

Hogan Lovells Publications

Proposed measures in Germany for safeguarding supply of critical goods in the combat against COVID-19

Hogan Lovells Publications

Highlights from the DigiHealth Leaders Conference: interoperability, reimbursement, patient centricity, and forging effective partnerships

Hogan Lovells Publications

DHSC Update on Medicines and Medical Devices Contingency Planning

Sponsorships and Speaking Engagements

Applying FDA's Rules in the New World of Online Marketing and Crowdsourcing