

## 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.

- Coverage and reimbursement
- Financing, distribution, and other agreements
- Good Clinical Practice (GCP) compliance
- Humanitarian device exemptions
- Import/export
- In vitro diagnostics
- Intellectual property
- Investigational Device Exemptions (IDEs)
- Litigation and internal investigations
- Post-market compliance and enforcement actions
- Pre-IDE submissions
- Premarket notification and pre-market approvals — 510(k)s and PMAs
- Product safety and liability
- Quality system regulation
- Reclassification petitions

## Contacts

Janice M. Hogan,  
Philadelphia

Jonathan S. Kahan,  
Washington, D.C.

Dr. Jörg Schickert,  
Munich

Elisabethann Wright,  
Brussels

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## Industries

Life Sciences and Health  
Care

- Requests for designation

## 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.

Managing PMA and Advisory Panel Process and helped secure approval for novel, noninvasive screening test using advanced DNA technology to detect colorectal cancer.

Drafting one of the first de novo submissions and obtaining multiple downclassifications and subsequent premarket clearances for capsule endoscopy imaging systems.

Assisting a client seeking FDA regulatory marketing approval of the first ever Retinal Prosthesis System intended for partial restoration of vision.

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

Assisting a client that manufactures an artificial heart to reverse Medicare's national noncoverage decision and secure more advantageous Medicare reimbursements.

Advising a U.S.-based national trade association that provides educational assistance to medical technology companies in Chinese medical device reimbursement rules and policies.

Acting for a global medical device manufacturer on various claims regarding cardiac devices.

Advising a U.S. medical devices company on regulatory and commercial issues regarding the market launch of a gene test in 24 European countries.

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.

Counsel to a publicly traded company in a voluntary disclosure to USDOJ and the SEC regarding alleged payments to win public tenders and in follow-on litigation.

Represented a global technology company in the creation of a joint venture to develop next-generation surgical robots.

We have prepared more companies for panel meetings in the last two years than almost any other law firm or consultant in the country.

## Latest thinking and events

### Hogan Lovells Publications

Harmonizing cybersecurity for medical devices: International collaboration moves forward

*Medical Device Alert*

### Hogan Lovells Publications

Clarifying clinical decision support: FDA overhauls guidance to focus on risk

*Medical Device Alert*

### Hogan Lovells Publications

Guidances galore: FDA finalizes multiple digital health guidance documents

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### Hogan Lovells Publications

FDA issues draft guidance on providing regulatory submissions in electronic format

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### Sponsorships and Speaking Engagements

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

### Hogan Lovells Publications

Final guidance provides additional clarity to the Humanitarian Device Exemption program

*Medical Device Alert*