



Medical Devices

The medical device industry is currently undergoing monumental change—from supply chain challenges to disruptive technologies and economic fluctuations. To pave the way for a more accessible and innovative health care landscape—including advances in wearables, implants, diagnostics, mobility, drug delivery—the evolving and expansive medical device industry faces wide-ranging legal needs. Clients in this sector can tap the remarkable depth and breadth of our sector-focused and skilled attorneys in the U.S. and abroad. Our Health Care & Life Sciences Industry Group engages clients at all points in the product development life cycle to provide sound advice and practical solutions regardless of the client's size or the complexity of their need. We help clients navigate today's complex regulatory landscape, defend products and reputations in the face of high-profile product liability and mass tort claims, protect innovative intellectual property (IP), and leverage cross-border experience to advise on commercial transactions.

Key Contacts

[Charles B. Klein](#)

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Areas of Focus

Medtech Patent Litigation

With more than 100 attorneys, our IP Practice is one of the most active and highly regarded in the U.S. In this legal discipline, very few firms offer as wide a spectrum as that of our life sciences and technology experience.

Technologies Covered by Our Practice

- Mechanical & Systems Engineering – products and devices designed to carry out specific functions, manufacturing, or process steps (e.g., medical devices, heat transfer, fluid control, and industrial process equipment)
 - Life Sciences & Biotechnology – genetically engineered and DNA-based technology; implantable devices; diagnostics, vaccines, probes, vectors, and cell lines; and related discoveries for application in compositions, treatments, and therapeutics
 - Electrical Engineering & Electronics— computer hardware, peripherals, and software; artificial intelligence; and digital devices
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Product Life Cycle Compliance

Our Health Care & Life Sciences Industry Group stands ready to meet our clients wherever they may be in the product development life cycle—research, commercialization, or distribution—to provide advice and practical solutions to clients, whatever the complexity of the need. We routinely draw from our extensive business and regulatory knowledge to help sector participants navigate the complete product life cycle, including:

- clinical research and development programs, including HIPAA privacy and consent;
 - sales and marketing compliance, including employee training on fraud and abuse and Code of Ethics;
 - marketing application strategies for drugs, biologics, and medical devices and U.S. state licensing requirements;
 - government Price Reporting obligations for Medicare, Medicaid, the Department of Veterans Affairs, and 340B;
 - the negotiation of customer and distributor supply agreements for both pharmaceutical manufacturers and medical device companies, including government purchasers under the Federal Supply Schedule (FSS);
 - design and execution of Patient Access programs (e.g., kickstart, patient assistance and co-pay assistance programs for pharmaceutical manufacturers, limited pharmacy distribution networks, and hub service vendors); and
 - international trade compliance, including country of origin.
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Mergers & Acquisitions

We have extensive experience advising clients on risk management concerns involving mergers and acquisitions, public policy, IP protection, and an array of regulatory compliance matters relating to product marketing, foreign bribery, and import/export controls.

Internal & Governmental Investigations & Related Litigation

With former DOJ attorneys and in-house attorneys embedded in our Health Care & Life Sciences Industry Group, our attorneys have extensive experience in matters involving state and federal government law enforcement and investigations, including federal False Claims Act (FCA) defense, internal investigations, fraud and abuse compliance training, congressional investigations, and health care litigation.

Related Capabilities

Commercial Litigation & Disputes

Employee Benefits & Executive Compensation

Environmental

Government Program Fraud, False Claims Act & Qui Tam Litigation

Intellectual Property

International Trade

Labor & Employment

Litigation/Trials

Mergers & Acquisitions

Patent Litigation

Private Equity

Privacy & Data Security

Trade Secrets, Non Competes & Restrictive Covenants

Health Care

Life Sciences

Recent Experience

Court Square Capital Partners in its Definitive Agreement to Sell Advanced Diabetes Supply Group for US\$1.1B

Docter Inc. and Aimfinity Investment Corp. I Announce Definitive Merger Agreement

Picard Medical and its Subsidiary, SynCardia Systems, Announce Business Combination with Altitude Acquisition Corp.

Culper Capital Partners's Acquisition of Ring Precision Components, New Vision Industries, and Dieco to form The Producto Group

Surgical Science Sweden AB's Acquisition of Simbionix

Incodema Holdings' Acquisition of Dahlquist Machine

Hospice Source's Acquisition of Superior Healthcare Inc.

United American Healthcare Corp. Sale of Pulse Systems LLC to Heraeus Holding GmbH

Won Rare Denial of Class Certification for Medtronic in Securities Fraud Litigation

Resources

[Product Liability & Mass Torts Digest](#)

Related Insights & News

SPEAKING ENGAGEMENT

Partners Imad Khan and Keerthika Subramanian Discuss Hot Topics in International Arbitration and Strategic Transactions in India as Part of Practising Law Institute Program

MAY 9, 2025

SPONSORSHIP

Winston & Strawn Sponsors Healthcare Business International 2025

MARCH 24, 2025

CLIENT ALERT

Executive Order Reemphasizes Healthcare Price Transparency

MARCH 4, 2025

SPEAKING ENGAGEMENT

Banee Pachuca to Teach Fraud and Abuse Course at the University of Houston Law Center

SPRING 2025

BLOG

New Theory for Establishing Causation Under California's Learned Intermediary Doctrine (*Himes v. Somatics*)

JULY 2, 2024

RECOGNITIONS

Winston & Strawn Recognized in *The Legal 500 U.S.* 2024

JUNE 12, 2024

BLOG

Eleventh Circuit Affirms CoolSculpting Device Manufacturer Win on Warning and Defect Claims

AUGUST 11, 2023

SPEAKING ENGAGEMENT

Ivan Poullaos Discusses How the Supreme Court's Enablement Ruling in *Amgen v. Sanofi* Will Affect Biologic Patent Portfolio Strategies

JUNE 27-28, 2023

CLIENT ALERT

Clarifying the Enabling Obligation of the Patent Act: *Amgen Inc. v. Sanofi*

JUNE 21, 2023

SEMINAR/CLE

Winston & Strawn's Product & Mass Torts Summit 2023

JUNE 14, 2023

BLOG

The FTC Attempts (Again) to Lay the Groundwork for Use of Its Penalty Offense Authority: This Time for Deceptive Product Claims

MAY 8, 2023

SPEAKING ENGAGEMENT

Kurt Mathas Speaks on Pharmaceutical Patent Litigation Settlements at Paragraph IV Disputes Conference

APRIL 19-20, 2023