



BRINGING TECHNOLOGY TO LIFE. *Representing innovative medical device manufacturers working to improve and enhance medical outcomes.*

The MedTech industry encounters a wide range of issues when bringing a product to market and keeping it on the market. From device design and development through clinical trials and regulatory clearance, to compliance, post-market surveillance and product liability concerns, medical device manufacturers face significant issues and challenges. We assist medical device manufacturers at every stage of a product's life cycle – protecting IP, negotiating supply and distribution contracts, reviewing licensing and partnership agreements, assisting with the regulatory review process, and mitigating and defending against the threat of products liability litigation.

As a full-service law firm, we use a multidisciplinary approach to advise clients on compliance with the complex issues that involve different legal areas, such as FDA compliance, antitrust laws, products liability tenants and intellectual property pathways. Our efforts are focused on balancing risk while promoting innovation.

Our attorneys provide counsel on the most effective methods of establishing and developing IP holdings and understand that a thorough and accurate IP asset due diligence review, aligning IP strategy with business goals, is essential to help companies acquire and protect IP rights, maximize their patent term and realize the most value from their assets.

We regularly assist clients in dealing with governmental regulatory agencies, including the FDA, Medicare and Medicaid Services, the Department of Health and Human Services, the U.S. Department of Justice, the FDA Office of Criminal Investigations and state regulatory authorities. Our experience includes representing clients in regulatory enforcement actions, internal investigations, fraud and abuse, off-label promotion and alleged violations of the Federal Food, Drug and Cosmetic Act.

We advise clients on critical partnering, licensing and financing transactions, as well as significant operational agreements for manufacturing and supply, distribution, and pre-clinical and clinical research. Our interdisciplinary teams routinely provide underwriting and deal diligence involving entities in the medical products space. We have also developed a compliance program and training related to Fraud and Abuse, off label promotion, and Sunshine Act reporting for medical device manufacturers.

We have also assembled a dedicated team of lawyers with significant experience in the many intersecting areas of law that fall under

the broad headings of “noncompete” agreements and “trade secrets,” including: drafting and reviewing restrictive covenants; advising clients on hiring, onboarding and retaining personnel from competitors; and aggressively pursuing and defending contract- and tort-based claims.

Finally, we help medical device clients strategically navigate through mass tort and individual, high-stakes, products liability litigation. We advise clients during the regulatory approval and device development process on steps to potentially mitigate products liability risks. In the event of litigation, we have vast experience in complex multiparty and multidistrict litigation at both the federal and state level—earning a Top-Tier ranking by U.S. News World Report for our mass tort litigation practice. We guide clients through all aspects of complex litigation, including general and expert discovery, strategic motion practice, selecting and conducting bellwether trials and structuring settlement programs.

RANKINGS

- ▶ Ranked by Legal 500: United States as a **LEADING LAW FIRM** in Life Sciences
- ▶ Ranked by LMG Life Sciences 2022 among leaders in Patent Prosecution



RANGE OF SERVICES

- ▶ IP Licensing/Diligence
- ▶ IP Strategy/Prosecution
- ▶ IP Litigation
- ▶ Regulatory
- ▶ Corporate Formation
- ▶ Financings
- ▶ Exits
- ▶ Stakeholder Disputes
- ▶ Collaborations/ Partnering
- ▶ Commercial Contracts
- ▶ Corporate Governance
- ▶ Commercial Litigation
- ▶ Products Liability and Toxic Torts
- ▶ White Collar/ Government Regulatory
- ▶ Employment and Labor
- ▶ Benefits
- ▶ Immigration Services and Compliance

REPRESENTATIVE MATTERS

- ▶ Represented a medical device manufacturer in federal multi district court and coordinated state court litigation involving over 2,000 claims alleging that metal-on-metal hip implant products were unreasonably dangerous. Obtained a complete defense verdict—upheld on appeal—on behalf of a metal on-metal hip implant manufacturer following a two-week jury trial in St. Louis, Missouri.
- ▶ Represented **GLOBAL SURGICAL INSTRUMENT** in a patent infringement case filed in Minneapolis involving expandable reamer for use in orthopedic implant surgery.
- ▶ Represented **STIFEL FINANCIAL CORP.** as sales agent in a \$50 million at-the-market (ATM) equity offering of common stock for Endologix Inc. (Nasdaq: ELGX). Endologix develops, manufactures, markets and sells medical devices for the treatment of aortic disorders.
- ▶ Represented **VESPER MEDICAL, INC.**, a private medical device company developing innovative venous stent solutions for peripheral vascular disease, in its \$37 million Series B Preferred Stock financing. Lead investors Vensana Capital and Gilde Healthcare were joined by existing investors New Enterprise Associates and Quaker Partners.
- ▶ Lead counsel defense of **PRESTIGE CONSUMER HEALTHCARE, INC.** in a Robinson-Patman Act price discrimination claim filed by 10 regional wholesalers in the United States District Court for the Central District of California.
- ▶ Represented **RUNWAY HEALTHCARE**—an accelerator that funds and manages the product development of emerging medical device companies and seeks to exit those companies before commercialization with at least 50 percent ownership—in acquiring control of Waypoint Orthopedics, which focuses on surgical solutions for the treatment of spinal disorders, and Toetal Solutions, which is developing the Ziptoe Hammertoe System.
- ▶ Represented **WRIGHT MEDICAL** in a patent infringement and trade secret misappropriation suit involving 10 patents related to bone plating systems and related distraction device.
- ▶ Represented **INTACT VASCULAR, INC.**, a developer of medical devices for minimally invasive peripheral vascular procedures, in its \$25 million Series C Preferred Stock extension financing, with Vensana Capital as the lead investor. Vensana was joined by existing investors, including New Enterprise Associates, H.I.G BioHealth Partners and Quaker Partners Management.
- ▶ Secured summary judgment for **BAXTER INTERNATIONAL**, a healthcare company focused on chronic illnesses, in a products liability matter involving a biologic patch used to repair a hernia that plaintiffs alleged was defective and caused pain, scarring and required a major revision.
- ▶ Represented **ALVOGEN** in connection with a generic “EpiPen-type” medical device, including conducting due diligence and a landscape search for freedom to operate.
- ▶ Advised a New Zealand-based leading designer, manufacturer and marketer of healthcare products in its proposed distribution transaction in Vietnam with concentration in competition law issues (including working with the National Competition Committee, the Unfair Investigation Division under the Ministry of Industry and Trade).
- ▶ Defended merger of prosthetics manufacturers against alleged violations of the Clayton Act and the Federal Trade Commission Act in Federal Trade Commission administrative proceeding.

- ▶ Represented **KEYSTONE HEART**, a privately held Israeli medical device company, in connection with a merger agreement for its multimillion dollar sale to Venus Medtech, a Chinese transcatheter heart valve company.
- ▶ Argued before the U.S. Court of Appeals for the Sixth Circuit on behalf of a multinational medical device corporation regarding a supplier’s breach of a patent infringement indemnification agreement.
- ▶ Represented **CANTOR FITZGERALD & CO.** as sole book-running manager in connection with a \$41.5 million bought deal offering of stock purchased for PAVmed Inc. (Nasdaq: PAVM), a multi-product, commercial-stage medical device company.

OFFICE LOCATIONS & REACH



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Houston
Lake Tahoe
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Miami
New York
Newark
Philadelphia
Pittsburgh
San Diego
San Francisco
Silicon Valley
Washington, D.C.
Wilmington

INTERNATIONAL

Hanoi
Myanmar
Ho Chi Minh City
Shanghai
London
Singapore

▶ Also satellite offices, including Bangor and Portland, Maine; and Seattle, Washington

▶ Alliances in Mexico

▶ Leadership position with international network of independent law firms

FOR MORE INFORMATION, PLEASE CONTACT:

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