

Medical Devices

Polsinelli's attorneys in the area of medical technology have decades of deep involvement with clients integral to the field of medical devices, including companies in the Fortune 500 and with annual revenue into the billions of dollars. They have executed hundreds of patent applications for medical device companies, and defended companies in the industry against product liability claims by individuals and certified classes. Polsinelli attorneys also have significant experience representing medical device companies in mergers, acquisitions, and other transactional corporate matters.

Health Care

The firm's health care attorneys provide strategic guidance to medical device companies on a broad range of issues, including clinical trials, sales and marketing operations (including direct-to-consumer marketing compliance), digital and telehealth counseling, coverage and reimbursement, and HIPAA and state privacy laws.

We also assist in the development and implementation of corporate compliance programs that address key compliance areas, including the development of policies and procedures, conducting risk assessments, and performing internal reviews, audits and investigations. Should inquiry or audit occur, we also have deep experience representing medical device manufacturers and suppliers in connection with criminal and civil litigation on matters involving the False Claims Act, the Foreign Corrupt Practices Act, federal and state fraud waste and abuse laws, enforcement actions by the DOJ, HHS-OIG, FDA and CMS, and other disputes.

Intellectual Property

In the universe of patents, those involving medical devices require extensive experience and cross-disciplined teams to protect and enforce the valuable inventions they cover. Polsinelli's medical device patent prosecution attorneys understand the technology behind these inventions, and have decades of deep involvement with clients integral to the field of medical devices, including representation of companies in the Fortune 500 with annual revenue into the billions of dollars.

Clients have engaged Polsinelli in all aspects of protecting medical devices. We have written and prosecuted patent applications, drafted opinions, negotiated licensing deals, assisted with asset sales and purchases, and litigated infringement lawsuits. We have represented companies offering a broad diversity of device types, ranging from radiation therapy devices, bone repair devices, cardiovascular implants, trocars, stents, catheters, wound closure devices, mesh implants, devices having a drug coating, wearable physiological monitoring devices, spinal implants, lab-on-a-chip, microfluidics, and a variety of other devices.

Products Liability

For over half a century, our attorneys have been committed to defending manufacturers in complex and high exposure cases, and on behalf of clients we have successfully managed class actions, multi-party litigation and insurance coverage disputes with impact to our clients into the hundreds of millions of dollars. The Polsinelli

Products Liability practice handles medical device disputes in federal and state courts across the country. Our work in this area includes defense in claims arising out of alleged product defect or contamination, exposure during clinical trials, breach of warranty, failure to warn, allegations of professional negligence, and personal injury.

Food & Drug Administration

A robust knowledge of the FDA regulatory regime, a deep understanding of the policies and objectives that FDA laws are intended to achieve, and a grasp of the nuances involved in medical device manufacturing and distribution allow the attorneys in our FDA practice to provide counseling and advocacy on a diversity of issues involving most types of medical devices. Additionally, we have significant recent experience counseling various clients regarding the scope of FDA scrutiny and the parameters of FDA's enforcement discretion regarding mobile medical applications and similar software-based mobile health products.

We are also very well-versed with FDA's 510K clearance and PMA approval processes, typically working closely with our clients' internal technical/scientific experienced professionals (or similar outside consultants) who are likely to prepare the technical submission documents for FDA's review division personnel. This approach has proven to maximize efficiency and places Polsinelli in a good position to address legal concerns that may arise as issues shift from a technical regulatory focus to more legal regulatory matters after a 510K clearance or PMA has been obtained.

Representative technologies include:

- Aneurysm treatment
- Blood clot removal
- Bone substitute materials
- Breast health monitoring and tumor detection
- Cardiac ablation
- Cardiac patient management
- Cardiac stents and associated deliver tools
- Carpal and cubital tunnel surgeries
- Dental tools and implants
- Diabetic neuropathy treatment
- Endoscopic and laparoscopic surgeries
- Implantable pulse generators, leads and associated delivery tools for cardiac and pain management applications
- Intubation
- Joint replacement implants
- Laboratory processing
- Liposuction
- Medical data mining
- Medical facility communication systems
- Medical fluid pathway connectors and valves
- Medical imaging, including MRI, CT and echocardiography
- Medicament administration including via injection and infusion
- Ophthalmological examination, surgery and implants
- Oral health products
- Pain management applications
- Patient transporting
- Personal protective equipment
- Physical therapy technologies
- Programmers for programming implanted pulse generators
- Prosthetics
- Robotic surgery
- Spine implants

- Stem cell harvesting
- Surgical filters
- Surgical planning and simulation
- Surgical tables
- Ventilators
- Wound healing

Matters

- Acted as counsel in \$20 million purchase of a medical device product line.
- Acted as counsel in \$50 million sale of a surgical products/devices product line.
- Acted as counsel in \$50 million acquisition of stock owned by minority shareholders of a medical device manufacturing company.
- Represented privately held medical device manufacturing business, with operations in the U.S., Great Britain and Canada in \$540 million sale of assets to a publicly traded Fortune 20 company.
- Assisted a private equity firm in connection with its investment in an aesthetic medical device company. The firm invested \$1,500,000 for a 25% ownership stake in the Company.
- Represented leading provider of medical device and other supplies company in large Cloud/IT Outsourcing transaction versus a major multinational technology company.
- Successfully represented the research and development arm of a regional hospital chain in commercializing its first medical device products.
- Defense of orthopedic physicians in a medical device investigation
- Defense of cardiologists in medical device investigation.
- Represented the medical device arm of a major public corporation in the \$85 million acquisition of a medical device business from a major public corporation.
- Secured dismissal of allegations of fraud under the False Claims Act brought by a qui tam relator against another medical device company.
- Conducted an investigation of a medical device supplier concerning potential anti-kickback and related issues.
- Defended an international medical device manufacturer in 58 separate lawsuits spanning over 5 years against allegations of product liability and negligence.
- Conducted extensive freedom-to-operate assessments of acquisition target for a leading medical device company.
- Achieved summary judgment of non-infringement for medical device company whose sales of replacement carbon dioxide absorbers were protected by the doctrines of patent exhaustion and permissive repair.
- Developed an international patent portfolio for a medical device company whereby patentability was assessed followed by preparation of detailed patent applications designed to protect the client's device.
- Represented medical device manufacturer in action against former employee and Chinese start-up venture, obtaining a \$2.3 billion damages finding by jury.
- Represented medical device company in patent infringement action, resulting in a \$31 million jury verdict.
- Represented medical device company in products liability actions enforcing federal preemption, obtaining numerous decisions.
- Represented medical device company in multiple proceedings protecting new hires, resulting in multiple decisions under California law.