Buchanan

SUPPORTING MEDICAL DEVICE DEVELOPMENT
FROM FILING STRATEGY THROUGH COMMERCIALIZATION

Launching a medical device can be complex and costly without the right counsel. Delays in Food and Drug Administration (FDA) approval, inadequate protection of intellectual property (IP) assets, or poor coverage for payment are all potential roadblocks that threaten commercialization. Our team deeply understands these challenges and can provide the roadmap to a successful medical device launch and business strategy.

Representing Device Companies and Helping Advance the State of Medicine

At Buchanan, we provide our clients with a unique value proposition– a one-stop shop for medical device legal and regulatory expertise and support. Not only can we provide FDA guidance to seamlessly usher your device through the submission and approval process, but we also offer a full suite of IP protection support to keep your concept safe. Plus, we can guide you through the coverage and payment process. Our medical device clients are advancing the state of medicine and saving lives – we make sure their product launches are successful and profitable.

FDA Filing Strategy and Support

As medicines, treatments, therapeutics, and medical devices become more complex, so are the regulatory reviews and approvals of these new products. The FDA regulates a wide array of medical devices, including laboratory-developed tests, mobile medical apps, and certain software functions. Our team of attorneys has extensive experience with the FDA and can help medical device companies first determine whether a technology requires FDA regulation. If the answer is yes, we provide counsel on making critical filing decisions to advance a company's business strategies, which could include a premarket approval (PMA), a 510(k) notification, or a de novo filing. The product may also be a combination product, requiring further strategizing and planning.

Our experience working closely with the FDA's Center for Devices and Radiological Health (CDRH) and its Digital Health Center of Excellence gives us a keen insight into how to best develop a strategy for approval, including today's high-tech advances in software, artificial intelligence (AI), and machine learning (ML). Making the right decisions from the start can help exempt the product from certain unnecessary regulatory burdens and accelerate the approval process. With decades of experience applying for FDA approval and clearance, our team can formulate a filing strategy, manage interactions with the FDA, anticipate and solve challenges, and help avoid costly delays in FDA approval or clearance.

EXPERIENCE

- Helped obtain FDA approval for a combination drug/medical device competitor generic product that was going after a market of over $100 million.
- Assisted a client with the regulatory strategy for how best to bring a medical device to market without having to obtain Pre-Market Approval from FDA.
- Converted a foreign company's medical device CE mark dossier to a 510(k) notification and guided the 510(k) through FDA clearance.
- Advised a client on importation of medical devices before FDA clearance.
- Advised clients on establishment registration and listing requirements for medical device companies throughout the supply chain.
- Advised clients on state licensing requirements for the manufacturing and distribution of medical devices across 50 states.
- Counseled clients on FDA requirements for 3D-printed orthopedic devices and AI/ML-based software as medical devices.

IP Protection

As all life sciences companies, investors, and manufacturers know, various IP issues come into play whenever a new medical device emerges. Protecting your IP and navigating the complex patent landscape is essential to the successful launch of all medical devices and must be considered early in the development process.

Working in close partnership with your technical and business leaders and internal legal staff, our team can craft an IP protection strategy tailored to your unique goals and challenges. We provide extensive industry-specific knowledge and highly relevant legal counsel to guide you through this process and avoid patent issues while ensuring all of your IP stays protected.

Reimbursement Counseling

Getting approval for reimbursement through private and government-sponsored insurance programs is a critical, yet often overlooked, aspect of maximizing the profitability of a new medical device. Without this approval, medical device companies potentially leave millions of dollars on the table each year.

Securing reimbursement for a product must be considered throughout the product's development lifecycle. Our attorneys can provide a short-term strategy for today, as well as develop a long-term vision that accounts for shifting government qualifications surrounding reimbursement options. Our team of attorneys can provide counsel on these requirements to ensure there are no issues down the line that could compromise the profitability of your product.

Clinical Trial Support

While some medical devices do not require clinical trials, others require the generation of robust safety and effectiveness data from appropriately conducted studies in human subjects. Properly preparing for and conducting a clinical trial to test a new medical device is no easy task. The process can be daunting, from complying with FDA's regulations to managing complications that may arise during and after the clinical trial.

We can help implement all necessary controls to avoid clinical trial fraud, an area that has come under intense scrutiny from the FDA and the U.S. Department of Justice (DOJ) since the COVID-19 pandemic. Our services include vetting CROs, negotiating clinical trial agreements, drafting informed consent documents, performing audits, and even increasing oversight for decentralized trials. With decades of experience, our life sciences team helps sponsors in the medical device industry get their products tested, approved, and on the market.

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EXPERIENCE

- Handled the patent and trademark procurement work and the enforcement of Supplier NDAs for a medical device client that developed the first objective, electronically determined test for stroke for use by EMS.
- Managed the entire patent portfolio for a global medical device manufacturer that services more than 160 countries across four distinct business segments: entry site management and lesion access, injection and infusion therapy devices, drug delivery devices, and cardiac catheterization lab consulting.
- Drafted and prosecuted patents and did opinion work for a global medical device company focused on cardiac rhythm management, vascular intervention, and electrophysiology.
- Handled the Inter Partes Review of a U.S. patent on behalf of a global manufacturer of oxygen ventilators regarding one of their methods and apparatus for controlling a ventilator.
- Drafted invalidity and non-infringement legal opinions on behalf of a global manufacturer on patents related to therapeutically coated medical devices.
- Conducted freedom-to-operate analyses on behalf of an NDA holder on patents related to diabetes management with insulin pens.
- Evaluated the regulatory status of investigational new devices to determine their ability to be used in research without prior clearance.
- Helped client assess whether its technology was a significant-risk device or a nonsignificant- risk device, and therefore whether institutional review board (IRB) approval was sufficient to begin clinical trials or if submission of an investigational device exemption (IDE) was also required.
- Represented a pharmaceutical company in the patent prosecution of a newly innovated wearable monitoring device.
- Represented a University Research Innovation Center in drafting and prosecuting their medical device patents related to biotemplating methods, cancer treatments, tumor treatments, PET imaging, genetic modifications, and more.

Product Marketing Expertise

With countless rules and regulations about how a medical device can be marketed once approved, it's important to fully grasp what companies can and cannot say when commercializing a new product. With FDA's recent renewed emphasis on fair balance in direct-to-consumer advertising, marketing will remain a focus area for the FDA, making it more important than ever for medical device companies to button up their approach when launching products to avoid costly investigations or delays that could hinder the product's commercial success. Our teams have experience reviewing marketing claims for medical device products to ensure they are legally promoting their product.

EXPERIENCE

- Reviewed marketing claims and pre-clearance marketing claims to ensure that a medical device company did not promote its product unlawfully including social media postings, web pages, banner ads, and conference booth materials.
- Provided regulatory strategy for the marketing and clearance of VR-based medical devices.

A Team of Tenacious Litigators

Whether it be a patent dispute or medical complaints filed by patients using your device, Buchanan has a multidisciplinary team of attorneys with decades of experience in healthcare and life sciences litigation. Our approach focuses on understanding the key legal, industry, and scientific issues that will likely be impactful in resolving or significantly narrowing litigation before trial. With specialists in biology, chemistry, physics and more, we can support your business through any disputes or lawsuits that arise.

REPRESENTATIVE TEAM

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