Greenleaf Health

MEDICAL DEVICES & COMBINATION PRODUCTS

GREENLEAF'S APPROACH

Greenleaf's in-depth knowledge and understanding of the U.S. Food and Drug Administration (FDA) provides clients with a trusted partner when navigating the complex process of bringing medical technologies to market.

Greenleaf's Medical Device and Combination Products Team guides clients through the complete regulatory process, from the earliest stages of product development, through the FDA review process, to marketing authorization and compliance with postmarket requirements and quality systems.

Greenleaf applies extensive regulatory expertise to determine the best regulatory approach for a product and develop a comprehensive strategy to achieve a successful result.

Additionally, Greenleaf's deep bench of FDA experts advises litigators representing FDA-regulated clients and provides authoritative, objective expert opinions in disputes involving regulatory issues, including complex commercial litigation, unfair competition and false advertising cases, intellectual property litigation, product liability class actions, and securities class actions.

Experts from Greenleaf's Medical Device and Combination Products Team also provide advisory services that include extensive research and due diligence for investors engaged in potential deals that require regulatory risk analyses before and after decisions and transactions.

To ensure success in today's rapidly evolving medical technology industry, companies must recognize and be prepared for a dynamic regulatory landscape. Guided by decades of experience, Greenleaf's team of experts provides unmatched knowledge of the life sciences regulatory process.

ABOUT GREENLEAF

Greenleaf Health is a leading FDA regulatory consulting firm that provides strategic and technical guidance to pharmaceutical, biotechnology, and medical device companies researching, developing, and manufacturing innovative solutions to pressing global public health challenges.

Greenleaf is committed to serving our clients' needs with extensive expertise, unwavering integrity, and strategic insight in a manner that supports availability of safe, effective, and high-quality drugs, biologics, and devices.

UNMATCHED EXPERTISE

Greenleaf's team is comprised of experts with a combined total of more than 300 years of FDA experience. The firm includes former leaders and regulatory professionals from the FDA, Capitol Hill, top global pharmaceutical and medical device companies, leading law firms, and the top U.S. biotechnology trade organization.

With decades of experience in senior positions at the FDA and throughout industry, Greenleaf's team of respected professionals brings unmatched expertise that companies need when working directly with the FDA and when navigating today's evolving regulatory environment.

Greenleaf is a regulatory consulting firm and does not provide legal advice or legal services.

MEDICAL DEVICE SERVICES

Unmatched Regulatory Experience
Strategic consultation on:

FDA's regulatory policies, programs, and procedures
Product development
Premarket review
Postmarket safety requirements
Market analysis for potential competition

Premarket Review Process
Experienced direction on:

Scientific and regulatory strategies for clinical programs and regulatory submissions

Recommendations and preparation for FDA meetings, including medical device advisory panel meetings

FDA communications, including formal, in-person, and regulatory correspondence

Regulatory Policy Guidance
Specialized insight on:

FDA policies and procedures

User fee requirements

Medical device advisory panel decisions and meeting preparation

Implementation of new FDA legislation, regulations, guidance documents, and FDA standard operating procedures

Marketing & Promotional Practices
Skilled support on:

Labeling requirements
Promotional materials
Direct-to-consumer advertising review processes
Remediation of untitled and warning letters
Use of social media

Litigation Support
Credible opinions via:

FDA institutional and regulatory knowledge-sharing
Expert declarations
Expert reports
Deposition testimony
Trial testimony

EXPERT TEAM

DAN SCHULTZ, M.D.
Principal, Medical Device & Combination Products
Former Director of the FDA's Center for Devices and Radiological Health (CDRH); distinguished 35-year career includes service as a physician, senior FDA official, and member of the U.S. Public Health Service.

HEATHER ROSECRANS
Executive VP, Medical Device & Combination Products
One of the nation's leading 510(k) experts, with an FDA career that spanned more than 30 years and included a pivotal role in developing the FDA's 510(k) program.

MAURA NORDEN
Senior VP, Medical Device & Combination Products and General Counsel
15 years of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

KATE COOK
Principal, Regulatory Policy
More than two decades of FDA experience that includes policy development and service as legal counsel on biological, medical device, and drug issues.

SAMANTHA EAKES
Director, Regulatory Affairs
Master's in Public Health from the Boston University School of Public Health provides critical public health, advocacy, and regulatory knowledge.

CATHERINE ROWE
Director of Operations, Medical Device & Combination Products
More than 20 years of professional experience in marketing, sales, and project management.

COMPREHENSIVE SERVICES

Members of the Greenleaf team work cross-functionally to provide a full-service engagement that ensures clients can count on expert direction as they encounter regulatory challenges. Greenleaf's collaborative services include:

Quality & Compliance Services

The Medical Device Team works closely with Greenleaf's Product Quality, Manufacturing, and Compliance Team to provide expertise in the FDA's compliance, inspection, and enforcement processes.

Advisory Services

Greenleaf understands the complex environment within which life sciences transactions take place and advises investors on potential issues and regulatory risks that may be identified during such transactions.