



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.

www.GreenleafHealth.com

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.



MARK KRAMER

Executive VP, Medical Device & Combination Products

17-year FDA career includes establishing and directing the Office of Combination Products and leading interdisciplinary review teams in CDRH.



MAURA NORDEN

Executive 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.



SAMANTHA EAKES

Vice President, 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

Executive 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:

Advisory Services

Greenleaf experts 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.

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.

Digital Health Services

Greenleaf Health serves as a trusted partner to both large and small clients developing and commercializing innovative digital health technologies as they navigate the complex landscape of FDA regulations and policies.

Regulatory Policy Services

Greenleaf provides support for stakeholders in communicating effectively about FDA regulatory policy issues and in understanding, implementing, and complying with the FDA's regulatory programs.