Greenleaf Health

MEDICAL DEVICES & COMBINATION PRODUCTS

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.

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.

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 250 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.

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

Expert 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

LEADERSHIP

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 (USPHS).

HEATHER ROSECRANS

Executive Vice President, 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 Vice President, Medical Device & Combination Products and General Counsel

More than a decade of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

KATE COOK

Executive Vice President, Drug & Biological Products

Two decades of experience in policy development and 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:

Compliance & Manufacturing 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 frequently advises investors to evaluate potential issues and regulatory risks that may be identified during such transactions.