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 and serves as a trusted partner for companies navigating the complexities of product lifecycle management.

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 delivers services that guide clients from early stage development to marketing authorization and throughout a product's lifecycle. The firm's Medical Devices and Combination Products Team offers strategic and technical guidance in key areas, including FDA submissions, FDA's review process and postmarket requirements such as safety monitoring and quality systems. Greenleaf makes this possible by applying extensive regulatory expertise, determining the best regulatory approach for a product and providing a comprehensive strategy to achieve a successful result.
- Greenleaf assists clients with all aspects of the regulatory review process for medical devices and combination products. Greenleaf also assists with the medical device submission process, such as the preperation of 510(k)s and PMAs, 513(g) requests, de novo petitions and HUD, HDE and IDE applications.
- Experts from Greenleaf's Medical Devices and Combination Products Team also provide advisory services that include extensive research and due diligence to firms engaged in potential mergers and acquisitions that require a regulatory risk assessment before and after a life sciences transaction.

ABOUT GREENLEAF

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

COMPREHENSIVE SERVICES

Greenleaf's Medical Devices and Combination Products Team spans the earliest stages of premarket production development and continues throughout a product's lifecycle.

GREENLEAF'S MEDICAL DEVICE SERVICES

Product Lifecycle Management

- Strategic guidance on FDA's regulatory process
- All aspects of product development
- Premarket review
- Postmarket safety requirements
- Analysis of the market to identify potential competition

Medical Device Product Submissions

- Request for Classification Information (513(g))
- 510(k) premarket notifications
- Premarket approval applications (PMAs)
- Requests for de novo review of automatic Class III classification
- Humanitarian use designation (HUD) / Humanitarian device exemption (HDE) applications
- Investigational device exemption (IDE) applications

Premarket Review Process

- Scientific, medical and regulatory guidance for clinical programs and regulatory filings
- Strategic guidance and preparation for FDA meetings, including medical device advisory panel meetings
- Analysis of, and recommendations on, FDA communications

Marketing & Promotional Practices

- Strategic guidance on labeling requirements
- Promotional materials
- Direct-to-consumer advertising review processes
- Remediation of untitled and warning letters
- Use of social media

Regulatory Policy Guidance

- Analysis of FDA policies and processes
- User fee requirements
- Medical device advisory panel meeting analyses
- Implementation of new FDA legislation, regulations, guidance documents and FDA standard operating procedures

Compliance & Manufacturing Services

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

Advisory Services

- Greenleaf regularly partners with investors to evaluate potential issues and regulatory risks identified during life sciences transactions.
- Greenleaf's advisory services include evaluations of the following potential sources of risk: marketing authorization, manufacturing, product safety, labeling, promotion, research and development and distribution and supply chain.

LEADERSHIP

Dan Schultz, MD

Principal, Medical Devices & Combination Products

Dan Schultz joined Greenleaf following a distinguished 35-year career devoted to supporting and advancing Americans' public health as a physician, senior FDA official and member of the U.S. Public Health Service (USPHS). Most recently, Dan served as Director of FDA's Center for Devices and Radiological Health (CDRH).

Heather Rosecrans

Executive Vice President, Medical Devices & Combination Products

Heather Rosecrans' FDA career spanned more than 30 years and included a pivotal role in developing FDA's 510(k) program. These accomplishments enabled her to become one of the nation's leading 510(k) experts.

Laurie Clarke

Executive Vice President, Medical Devices & Combination Products Laurie Clarke brings more than 25 years of leadership as an FDA attorney – including experience as a partner at three leading Washington, DC law firms – to her role at Greenleaf Health.

Maura Norden

Senior Vice President, Medical Devices & Combination Products

General Counsel

Maura Norden joined Greenleaf from the law firm Sidley Austin LLP, following nearly a decade of professional experience advising leading medical device and drug companies on a broad range of FDA regulatory matters.

ADDITIONAL TEAM MEMBERS

Brian Corrigan | Jason Campbell | Catherine Rowe