Greenleaf Health

# MEDICAL DEVICE PRODUCT SUBMISSIONS

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 delivers services that guide clients from early stage development to marketing authorization and throughout a product's lifecycle.

## GREENLEAF'S APPROACH

- In a constantly changing regulatory environment, medical device companies need a comprehensive, forward-looking strategy and a well-versed strategic partner to support the growth of their innovative technologies and successfully bring new products to market.
- 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 devices to market.
- The firm's Medical Devices and Combination Products Team offers strategic and technical guidance on all aspects of the medical device submissions process, including the preparation of 510(k) and PMA submissions, 513(g) requests, de novo petitions, HUD, HDE, IDE applications, pre-submissions, and requests for designation of a combination product.
- In addition to submission services, Greenleaf's team of experts guides clients throughout a product's lifecycle, including early stage development and postmarket requirements.
- Greenleaf's experts leverage their extensive regulatory expertise to determine the best regulatory approach for a product, develop a comprehensive strategy to achieve a successful result and assist the company in implementing the strategy.

## 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 assists clients with all aspects of the submission process for medical devices and combination products.

# GREENLEAF'S MEDICAL DEVICE PRODUCT SUBMISSION SERVICES

**Premarket Preparation**

- Combination product designations
- Requests for device classification (513(g))
- Presubmission strategy
- Identification of predicate devices
- Determination of and compliance with performance data and labeling requirements
- Demonstration of substantial equivalence/safety and effectiveness

**Premarket Submissions**

- 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
- Request for designation (RFD) of devices

**Premarket Review Process**

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

**Marketing & Promotional Practices**

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

# PRODUCT LIFECYCLE SERVICES

**Product Lifecycle Management**

- Strategic guidance on FDA's regulatory process
- Postmarket safety requirements
- Analysis of the market to identify potential competition

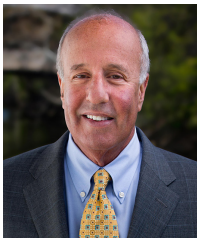
**Regulatory Policy Guidance**

- Analysis of FDA policies and processes
- User fee requirements
- Medical device advisory panel meeting analysis
- 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.

# 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. Most recently, Dan served as Director of FDA's Center for Devices and Radiological Health.

## 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, D.C. law firms – to her role at Greenleaf Health.

## Maura Norden

***Senior Vice President,***
***Medical Devices & Combination Products***

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.

## Jason Campbell

***Director,***
***Medical Devices & Combination Products***

Jason Campbell's familiarity with FDA statutes and policies, coupled with his experience drafting medical device submissions and performing legal research, provide a valuable asset to Greenleaf clients.

# ADDITIONAL TEAM MEMBERS

Brian Corrigan | Catherine Rowe