Greenleaf Health

# Laurie Clarke, J.D., M.P.P.

## Executive Vice President, Medical Devices & Combination Products

| | |
|---|---|
| BACKGROUND | • FDA partner in three international law firms with top medical device practices |
| AWARDS | • Ranked as a top FDA lawyer by The Legal 500<br>• Received mentor award from global law firm based on nominations from associates |
| EXPERIENCE | • More than 25 years of experience as an FDA lawyer in Washington, DC<br>• Co-founded the FDA practice at the largest U.S. law firm<br>• Led the FDA regulatory device practice at the third largest law firm worldwide<br>• Led the premarket submission group at the firm with the top-ranked FDA/ device practice |

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

Prior to joining Greenleaf Health, Laurie co-founded the FDA practice at Jones Day and led the device component of the law firm's practice. In this role, she dealt with premarket submission issues, FDA enforcement actions, Agency inspections, and off-label claims. Laurie helped clients ranging from start-up companies to multinational corporations develop and implement successful regulatory strategies.

During her more than eight years at King & Spalding, LLP, Laurie guided clients through a variety of regulatory hurdles as the leader of the firm's device premarket submission practice. In this capacity, she obtained 510(k) clearance for a wide range of devices and audited the regulatory status of numerous cleared/approved devices. In addition, Laurie led an international investigation of clinical study sites in India that found multiple violations. Laurie also assisted a company in addressing FDA's safety concerns about an implantable device at its facility in Australia. She successfully represented manufacturers of medical devices on a wide range of other premarket and postmarket FDA issues. She received the firm's mentor award based on nominations from the FDA associates.

At Hogan & Hartson, LLP, Laurie spent more than 11 years helping clients obtain FDA clearance/approval of 510(k) premarket notifications, premarket approval applications ("PMA"), investigational device exemption ("IDE") applications, and de novo review submissions. In addition, she conducted labeling reviews. She frequently advised clients about FDA's regulations regarding financial disclosure by clinical investigators.

Laurie began her legal career at Patton Boggs, where she worked on FDA regulatory matters involving foods, drugs, devices, and biologics. In addition, she negotiated an agreement with the publisher of the Nancy Drew mystery series to include an acknowledgement in the books that her client wrote the original stories under the pen name "Carolyn Keene."

Laurie earned an A.B. cum laude from Smith College, an M.P.P. from Harvard University, and a J.D. from Stanford University. Laurie's writing has appeared in several legal publications. She is a frequent speaker regarding FDA's regulation of medical devices. Her honors include being ranked as a top FDA lawyer by The Legal 500.