Hogan Lovells

John J. Smith, M.D., J.D.

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Biography

As both a physician and a lawyer, John Smith combines clinical and regulatory experience relating to the Food and Drug Administration (FDA) with a practical approach to addressing the FDA regulatory issues facing his clients. He places a particular focus on bringing device-based technologies to market.

A board-certified diagnostic radiologist and former associate professor of radiology at Harvard Medical School, John joined the Hogan Lovells Medical Device Group in 2005. Since then, he has assisted clients in a range of FDA premarket submissions, including 510(k) notices, de novo reclassification petitions, humanitarian device exemption applications, and premarket approval applications, including the advisory panel process.

John identifies successful regulatory strategies and presents them to the FDA via the pre-submission process; he assists with problem submissions through submission-issue meetings and administrative appeals. He also navigates the increasingly challenging FDA compliance landscape, addressing 483 and Warning Letter issues.

Bringing new products to the U.S. market is continually complex and demanding. Having worked in the medical device area in academia, industry, and at Hogan Lovells, John understands how to address both pre- and postmarket FDA regulatory issues. His practical approach has guided clients through successful marketing applications, addressed significant differences of opinion with the FDA through submission-issue meetings and regulatory appeals, and provided crucial support through challenging FDA enforcement actions. To serve his clients, John draws on the broad experience and skills of his colleagues in the Medical Device Group and effectively communicates with reviewers and decision makers at the FDA. A *Super Lawyers* designee for multiple years, John is a leader in the medical device bar and well known to the FDA.