Hogan Lovells

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

Partner

Washington, D.C.

Phone

+1 202 637 5600

Fax

+1 202 637 5910

Email

john.smith@hoganlovells.com

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

Languages

English

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Advertising and Promotion Compliance

Combination Products

Medical Devices

Premarket Review

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.

Representative experience

Assisting with submissions for diagnostic and therapeutic medical devices, including pre-subs, IDEs, 510(k)s, de novo reclassifications, and PMAs.

Preparing clients for successful advisory panel meetings for first-in-class medical devices, as well as reclassification petitions.

Assisting clients in successful utilization of the submission-issue meeting request process.

Representing multiple clients in successful supervisory appeals at the Center for Devices and Radiological Health.

Assisting a client in obtaining a direct de novo reclassification for a first-in-class medical device without the need for clinical data.

Assisting a client in the preparation of successful humanitarian use device and humanitarian device exemption applications.

Advising multiple clients regarding advertising and promotional issues related to cleared and approved medical devices.

Awards and rankings

- BTI Client Service All-Stars, *BTI Consulting Group*, 2018
- FDA: Food and Drugs, *Washington, D.C. Super Lawyers*, 2014-2015
- Editor's Recognition Award for Reviewing with Special Distinction, Radiology, 2002-2004

Digital Health

Advisory Panel Preparation

Medical Device Artificial Intelligence

Education and admissions

Education

J.D., University of Virginia School of Law, Order of the Coif, 1993

M.D., University of Virginia, 1992

B.A., Brown University, magna cum laude, 1986

Memberships

Chair, Committee on Resolutions and Bylaws, Radiological Society of North America

Member, American College of Radiology

Member, Virginia State Bar

Bar admissions and qualifications

District of Columbia

Virginia (inactive)

- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), *Chambers USA*, 2020

Latest thinking and events

- News
  - Evolution of FDA regulation of AI-based technology
- Hogan Lovells Events
  - Health Care AI Law and Policy Summit
- News
  - HHS proposal to exempt medical devices from 510(k) process halted
- News
  - Five highlights from FDA's new AI device regulation Action Plan
- Hogan Lovells Publications
  - Helping companies navigate the COVID-19 pandemic
- Insights
  - Variable De Novo review metrics -- Plan ahead