Jonathan S. Kahan

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With more than 40 years of legal experience, Jonathan Kahan is an industry leader in obtaining FDA market clearance of novel medical devices for medical technology and diagnostics companies. He also advises on post-market compliance matters.

Jonathan helps clients navigate complicated regulatory processes, including those related to combination products such as combinations of devices, drugs, biologics, and human tissues. He authored the leading text on medical device law, *Medical Device Development: Regulation and Law* (Parexel 2020).

Jonathan is the former director of the firm's Medical Device and Technology practice group and an adjunct professor at the George Washington University Law School teaching medical device law. He presently serves as a member of the George Washington University President's Leadership Advisory Council and he is also the general counsel of the Association of Medical Diagnostics Manufacturers.

Jonathan is highly ranked by *Chambers* as well as other legal directories. He has been consistently included in Washington, D.C. *Super Lawyers* and *Washingtonian* magazine's Top Lawyers in D.C. He also received the Food and Drug Law Institute (FDLI) Distinguished Service and Leadership Award, recognizing his contribution in promoting public health, advancing the medical device and technology law field, and ensuring a robust and innovative regulatory environment.

Representative experience

- Assisted client in obtaining premarket approval (PMA) for a novel medical device to treat brain cancer.
- Assisted client in obtaining a Humanitarian Device Exemption approval for a novel device that brings sight to patients blinded by retinitis pigmentosa.
- Represented a medical device client in resolving a civil money penalty proceeding brought by the FDA.
- Assisted client in obtaining de novo reclassification for a novel pill camera for imaging lesions in the colon.
- Assisted clients in obtaining 510(k) clearance for multiple proton beam therapy systems.
- Assisted client in obtaining PMA for a novel gastric balloon system for the treatment of obesity.
- Assisted numerous clients in the filing of a Requests for Designation with the FDA OCP and obtaining a favorable device jurisdictional rulings.
- Advised client regarding whether clinical decision software was regulated by the FDA as a medical device.