SETON HALL | **LAW**

Healthcare Compliance
Certificate Program

Kristin R. Davenport

Partner
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Kristin Davenport advises medical device companies regarding premarket strategies and pathways, the premarket submission process, advertising and promotion, compliance and enforcement matters, and import/export issues.

She has extensive experience with 510(k) premarket notifications, de novo petitions, premarket approval applications, investigational device exemptions, device modifications, 513(g) Requests for Information, MDR reporting, device recalls, and Part 806 reports.

Kristin regularly prepares 513(g) Requests for Information to obtain FDA's views regarding the classification and applicable regulatory requirements for novel devices, such as mobile medical applications. She develops successful premarket strategies for clients, and frequently participates in pre-submission meetings with CDRH. Kristin navigates issues that arise during the premarket review process, and has successfully represented device companies in administrative appeals. She also assists and represents clients in compliance and enforcement proceedings, including responding to FDA Form 483s and Warning Letters.

Kristin advises on jurisdictional questions and assists clients with combination product issues, including submitting Requests for Designation to the Office of Combination Products.