October 26, 2026

When AI Becomes a Medical Device: FDA Boundaries for Patient-Facing Health Tools

When does an AI health tool cross the line into a regulated medical device?

Day Pitney Attorneys Richard B. Emmons, Ph.D., and Jacob Golan, Ph.D., explore that question in *MedTech Insight*, examining how intended use, design, and functionality can trigger FDA oversight and why disclaimers alone may fall short.

The article explains the requirements for excluding certain clinical decision support functions from device regulation, including preserving clinicians' independent judgment. It also highlights the challenges of patient-facing AI and why regulatory considerations matter from initial design through post-launch monitoring.

Read the article to learn how AI design choices can shape FDA oversight and what developers should consider before and after launch.

Authors



Jacob Golan, Ph.D.

Associate

Stamford, CT | (203) 977-7320

Boston, MA |

jgolan@daypitney.com



Richard B. Emmons, Ph.D.

Partner

Boston, MA | (617) 345-4720

remmons@daypitney.com