

Regulating Digital Health Tools

Understanding the FDA’s New Guidances

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- C. FDA Guidance: *Medical Device Accessories – Describing Accessories and Classification Pathways*
- D. FDA Guidance: *General Wellness – Policy for Low Risk Devices*
- E. FDA Guidance: *Software as a Medical Device (SAMM) – Clinical Evaluation (IMDRF)*
- F. FDA Draft Guidance: *Multiple Function Device Products – Policy and Considerations*