FDA Classification Overview for Digital Health Products

Digital Health Regulatory Pathways

CLASS	RISK	POTENTIAL HARM	REGULATORY CONTROLS	% DEVICES IN CLASS*	EXAMPLES
I	**Lowest risk**	Lowest risk products Subject to only general controls Most Class I products are “exempt” from premarket notification	General	**35%**	Podimetrics SmartMat™, Visibly Digital Acuity Product
II	**Moderate risk**	Higher risk than Class I but lower risk than Class III Subject to general controls and special controls Requires premarket notification	General and special (if applicable)	**53%**	reSET-O, DeepRhythmAI, Tidepool Loop, Eko Murmur Analysis Software, BlueStar
III	**Highest risk**	Highest risk to patients - usually life-supporting, life-sustaining, or used to prevent unreasonable risk of illness or injury Subject to general controls and special controls Requires premarket notification	General and Premarket Approval (PMA)	**9%**	Freestyle Libre 14-day Flash CGM, VNS software, Pacing system analyzer by Abbott

Source: FDA, US RegPath Project team analysis

*3% of devices are unclassified

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