

Comparison Chart

for the U.S. Regulatory Pathways

DIGITAL HEALTH PRODUCTS

Category	510(k)	De Novo	PMA (Premarket Approval)	HDE (Humanitarian Device Exemption)
FDA Oversight Language	Cleared	Granted	Approved	Approved
Risk	Low to Moderate	Low to Moderate	High	Moderate to High
Medical Device Product Class	Class I, II	Class I, II	Class III	Class II, III
Control	General Controls Special Controls	General Controls Special Controls	General Controls Special Controls Pre-market Authorization	General Controls Special Controls Pre-market Authorization
Safety	No Substantial Equivalence	Reasonable Assurance of Safety	Reasonable Assurance of Safety	Will not expose patients to an unreasonable or significant risk of illness or injury
Effectiveness		Reasonable Assurance of Effectiveness	Reasonable Assurance of Effectiveness	Exempt from demonstrating effectiveness
Clinical Data	Sometimes require clinical data	Yes	Always require clinical data	Demonstration of Probable Benefit
Timeline	90 days (traditional and abbreviated) 30 days (Special)	150 days	180 days	75 days

User Fee (subject to change annually)	Standard Fee: \$12,745 Small Business Fee: \$3,186	Standard Fee: \$132,464 Small Business Fee: \$33,116	Standard Fee: \$441,547 Small Business Fee: \$110,387	No fee
Annual Reporting Requirement	No	No	Yes	Yes
GMP (Good Manufacturing Practice) pre-market review	No	Yes	Yes	Yes
MDR (Medical Device Reporting) requirement	No	Yes	Yes	Yes
Examples	<ul style="list-style-type: none"> • reSET-O by Pear Therapeutics • Tidepool Loop by Tidepool • d-Nav Technology by Hygieia • BlueStar by Welldoc • Eko Murmur Analysis Software (EMAS) by Eko Devices, Inc. 	<ul style="list-style-type: none"> • Paige Prostate by Paige. AI • Irregular Rhythm Notification Feature by Apple • Dexcom G6 CGM System by Dexcom • ContaCT by Viz.AI • ECG Application by Apple 	<ul style="list-style-type: none"> • Freestyle Libre 14-day Flash CGM by Abbott • Minimed CGM by Medtronic • VNS therapy system programming software by LivaNova • Pacing system analyzer by Abbott 	<ul style="list-style-type: none"> • Activa Dystonia Therapy System by Medtronic Neuro-modulation • CentriMag Right Ventricular Assist System (RVAS) by Abbott

Access DiMe's Digital Health Regulatory Pathway Resources



Identify your regulatory pathway



Build your regulatory strategy



Interact with regulators

