

How AI is used in FDA-authorized medical devices: a taxonomy across 1,016 authorizations

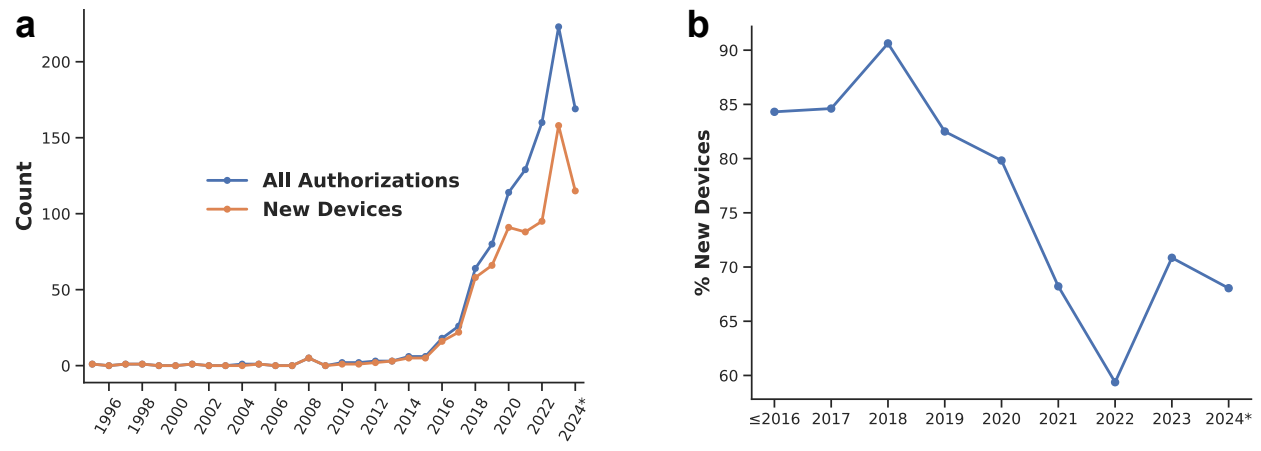
Supplementary Information

Supplementary Data 1: FDA AI taxonomy database. The curated taxonomy database is included as a spreadsheet.

Supplementary Table 1: Counts of devices and authorizations across all taxonomy factors.

Factor	Class	Unique Devices		All Authorizations	
		Count	%	Count	%
Data Type	Images	621	84.4	878	86.4
	Signals	107	14.5	128	12.6
	Omics	5	0.7	7	0.7
	EHR	3	0.4	3	0.3
Clinical Function	Assessment	619	84.1	849	83.6
	Intervention	117	15.9	167	16.4
AI Function	Generation	106	14.4	174	17.1
	Analysis	653	88.7	875	86.1
AI Function Subclass	Quant./feat. localization	427	58.0	576	56.7
	Triage	84	11.4	105	10.3
	Detection	45	6.1	64	6.3
	Diagnosis	47	6.4	60	5.9
	Detection/diagnosis	40	5.4	58	5.7
	Predictive	11	1.5	14	1.4
	Image enhancement	84	11.4	140	13.8
	Acquisition guidance	17	2.3	26	2.6
	Synth. data generation	8	1.1	14	1.4

Supplementary Figure 1: Number of authorizations and new devices over time. a) Counts from 1995 to 2024 (*up to September 27th for 2024). b) Percentage of authorizations that represent new devices.



Supplementary Figure 2: Counts and percentages of new devices per year for each of the taxonomy factors. *Up to Sept. 27th for 2024.



Supplementary Figure 3: Counts and percentages of all authorizations per year for each of the taxonomy factors. *Up to Sept. 27th for 2024.

