

Table 1: FDA-Approved AI Tools for Breast Cancer Screening

Note: AI tools are evolving rapidly, with new AI tools, additional FDA clearances, and ongoing acquisitions that may change the commercial landscape.

Product	Company (Country)	Density Assessment ^a	Cancer Detection ^b	Risk Prediction ^c	Primary Modality
Lunit INSIGHT MMG	Lunit (South Korea; formerly Volpara Health Technologies, New Zealand)	✓	✓	-	2D Mammography, DBT
Breast Suite	DeepHealth (RadNet, USA; formerly iCAD AI products)	✓	✓	-	2D Mammography, DBT
Quantra	Hologic (USA)	✓	-	-	2D Mammography, DBT
Transpara	ScreenPoint Medical (Netherlands)	✓	✓	-	2D Mammography, DBT
WRDensity	WhiteRabbit.ai (USA)*	✓	-	-	DBT
Densitas	Densitas Inc. (Canada)	✓	-	-	DBT
Genius AI Detection	Hologic (USA)	-	✓	-	DBT
Mammoscreen	Therapixel (France)	-	✓ ^d	-	2D Mammography
Clarity	Clarity Inc. (USA; based on the MIRAI model)	-	-	✓	2D Mammography, DBT
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Abbreviations: DBT = Digital Breast Tomosynthesis (3D mammography)

^a **Mirai** (MIT CSAIL, USA) and **LIBRA** (University of Pennsylvania, USA) are open-source research-use tools, not FDA approved, that provide quantitative density assessment and are not commercially available. LIBRA is freely available for download for research purposes, whereas Mirai is available upon request for research use.

^b **cmAssist** (CureMetrix, USA) is designed for cancer detection and is currently under development and not FDA approved.

^c **Mirai** (MIT CSAIL, USA) is available upon request for research use and provides risk assessment, but is not FDA approved; **Clairity** is based on the Mirai model and is FDA approved for risk assessment. **WRRisk** (WhiteRabbit.ai, USA) is an AI-based breast cancer risk prediction tool that incorporates established clinical risk models, including the Tyrer-Cuzick (IBIS) and Gail models, and does not have FDA approval.

^d **Mammoscreen** also provides, and is FDA-cleared for, triage functionality. **cmTriage** (CureMetrix, USA) is FDA-cleared for workflow optimization and case triage. **Vara Workflow** (Vara, Germany) is CE-certified for workflow optimization and case prioritization in breast cancer screening.