

K260087 Senographe PristinaMar 24, 2026
71 days to decisionK260087 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k260087/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Jan 12, 2026
Decision date	Mar 24, 2026
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SenoBright HD; Pristina Serena; Pristina Serena Bright

APPLICANT

Company	GE Medical Systems SCS
Location	Buc Cedex, FR
Contact	Fayçal Kherra
510(k) history	37 submissions · 37 cleared · 2008-2026

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