

K131885 SENOGRAPHE ESSENTIAL, PREMIUM VIEW I (PVI)Sep 26, 2013
93 days to decisionK131885 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k131885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Jun 25, 2013
Decision date	Sep 26, 2013
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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