

K103485 SENOGRAPH DS, SENOGRAPH ESSENTIALOct 6, 2011
314 days to decisionK103485 · Product code: **MUE** · Radiology
Source: <https://www.510kdatabase.net/k103485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Nov 26, 2010
Decision date	Oct 6, 2011
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	General Electric Company
Location	Waukesha, WI, US
Contact	STEVEN KACHELMEYER
Website	http://www.ge.com/
510(k) history	2 submissions · 2 cleared · 2011-2011

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