

**K133144 SONOSURE SONOHYSTEROGRAPHY &
ENDOMETRIAL SAMPLING DEVICE**Mar 19, 2014
153 days to decisionK133144 · Product code: **PGK** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k133144/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Injector, Uterine, Endometrial Biopsy (PGK)
Date received	Oct 17, 2013
Decision date	Mar 19, 2014
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Crossbay Medical, Inc.
Location	Irvine, CA, US
Contact	CINDY DOMECUS
510(k) history	3 submissions · 3 cleared · 2014-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133144/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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