

K151639 ABL80 FLEX and ABL80 FLEX CO-OXDec 7, 2015
172 days to decisionK151639 · Product code: **CGA** · Chemistry
Source: <https://www.510kdatabase.net/k151639/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Jun 18, 2015
Decision date	Dec 7, 2015
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sendx Medical, Inc.
Location	Carlsbad, CA, US
Contact	VIBEKE AGERLIN
510(k) history	6 submissions · 6 cleared · 1997-2015

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