

K051279 CALDYNE, INC. EXHALOMETER EX100, MODEL EX100Sep 7, 2005
113 days to decisionK051279 · Product code: **BZK** · General Hospital
Source: <https://www.510kdatabase.net/k051279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Monitoring (w/wo Alarm) (BZK)
Date received	May 17, 2005
Decision date	Sep 7, 2005
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Caldyne, Inc.
Location	Temecula, CA, US
Contact	TOM SHANKS
510(k) history	1 submissions · 1 cleared · 2005-2005

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