

**K121587 BREATH SHAKE**Nov 22, 2013  
540 days to decisionK121587 · Product code: **BYI** · Anesthesiology  
Source: <https://www.510kdatabase.net/k121587/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Percussor, Powered-electric (BYI)
Date received	May 31, 2012
Decision date	Nov 22, 2013
Days to decision	540 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cheen Houg Ent. Co. , Ltd.</b>
Location	Taipei (Shulin), TW
Contact	PAUL DRYDEN
510(k) history	6 submissions · 6 cleared · 1997-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121587/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026