

**K080921 SPIRO-MASTER PC-10 SPIROMETRY SYSTEM**Jan 21, 2009  
295 days to decisionK080921 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k080921/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Apr 1, 2008
Decision date	Jan 21, 2009
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chest M.I., Inc.</b>
Location	Tokyo, JP
Contact	FUMIAKI KANAI
510(k) history	2 submissions · 2 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080921/> 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