

**K093007 ENTELLUS MEDICAL BALLOON DEVICE**Feb 5, 2010  
130 days to decisionK093007 · Product code: **LRC** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k093007/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Sep 28, 2009
Decision date	Feb 5, 2010
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Entellus Medical, Inc.</b>
Location	Maple Grove, MN, US
Contact	Sew-Wah Tay
510(k) history	27 submissions · 27 cleared · 2008-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093007/> 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