

**K100995 SHIKANI SPEAKING VALVE**Jun 25, 2010  
77 days to decisionK100995 · Product code: **JOH** · Anesthesiology  
Source: <https://www.510kdatabase.net/k100995/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Apr 9, 2010
Decision date	Jun 25, 2010
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shikani Medical, LLC</b>
Location	Bonita Springs, FL, US
Contact	PAUL DRYDEN
510(k) history	1 submissions · 1 cleared · 2010-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100995/> 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