

**K122932 SPIRO SPEAKING VALVE WITH OXYGEN PORT SPIRO
SPEAKING VALVE WITHOUT OXYGEN PORT**Dec 23, 2013
455 days to decisionK122932 · Product code: **JOH** · Anesthesiology
Source: <https://www.510kdatabase.net/k122932/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube Tracheostomy And Tube Cuff (JOH)
Date received	Sep 24, 2012
Decision date	Dec 23, 2013
Days to decision	455 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fogless International AB
Location	Vaggeryd, SE
Contact	JASON WALTON
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122932/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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