

**K201472 VenSure Balloon Device, VenSure Nav Balloon Device**Aug 26, 2020  
84 days to decisionK201472 · Product code: **LRC** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k201472/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jun 3, 2020
Decision date	Aug 26, 2020
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fiagon GmbH</b>
Location	Hennigsdorf, DE
Contact	Dirk Mucha
510(k) history	15 submissions · 15 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201472/> 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 26, 2026