

**K230065 VenSure™ Balloon Dilation System, VenSure™ Light Balloon Dilation System, VenSure™ Nav Balloon Dilation System, VenSure™ ET Balloon Dilation System**May 26, 2023  
137 days to decisionK230065 · Product code: **PNZ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k230065/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eustachian Tube Balloon Dilation Device (PNZ)
Date received	Jan 9, 2023
Decision date	May 26, 2023
Days to decision	137 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/k230065/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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