

K223542 TubaVent Balloon Dilatation SystemAug 3, 2023
251 days to decisionK223542 · Product code: **PNZ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k223542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eustachian Tube Balloon Dilation Device (PNZ)
Date received	Nov 25, 2022
Decision date	Aug 3, 2023
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spiggle & Theis Medizintechnik GmbH
Location	Overath, DE
Contact	Claudia Winterschladen
510(k) history	1 submissions · 1 cleared · 2023-2023

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