

K220027 Audion ET dilation systemApr 12, 2022
97 days to decisionK220027 · Product code: **PNZ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k220027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eustachian Tube Balloon Dilation Device (PNZ)
Date received	Jan 5, 2022
Decision date	Apr 12, 2022
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Entellus Medical, Inc.
Location	Maple Grove, MN, US
Contact	Katie Wilson
510(k) history	27 submissions · 27 cleared · 2008-2022

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