

K163509 XprESS ENT Dilation SystemApr 5, 2017
111 days to decisionK163509 · Product code: **PNZ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k163509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eustachian Tube Balloon Dilation Device (PNZ)
Date received	Dec 15, 2016
Decision date	Apr 5, 2017
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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