

**K232702 Solo+ Tympanostomy Tube Device (TTD)**May 20, 2024  
258 days to decisionK232702 · Product code: **ETD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k232702/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tympanostomy (ETD)
Date received	Sep 5, 2023
Decision date	May 20, 2024
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aventamed Dac</b>
Location	Bishopstown, IE
Contact	Keith Jansen
510(k) history	2 submissions · 2 cleared · 2024-2025

**CLINICAL EVIDENCE - NCT04148417****Clinical Study of the Solo+ Tympanostomy Tube Device**

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Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	27 patients (estimated)
Study sites	2 sites
Condition studied	Ear Infection; Otitis Media
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Sep 1, 2024
Sponsor	AventaMed DAC (Industry)

**Primary outcome****Successful delivery of the tympanostomy tube by the Solo+ Tympanostomy Tube Device**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04148417](https://clinicaltrials.gov/study/NCT04148417)