

**K250256 Solo+ Tympanostomy Tube Device (TTD), Solo+ TTD, Solo+ (Solo+ Tympanostomy Tube Handpiece (Catalogue #: 12115-100-000) and Solo+ Tympanostomy Tube Cartridge (Catalogue #: 12115-200-000))**

Apr 28, 2025  
90 days to decision

K250256 · Product code: ETD · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k250256/>

**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tympanostomy (ETD)
Date received	Jan 28, 2025
Decision date	Apr 28, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**CLINICAL EVIDENCE - NCT05741333**

**In-Office Clinical Study of the Solo+ TTD**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	66 patients (estimated)
Study sites	7 sites
Condition studied	Ear Infection; Otitis Media
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 1, 2028
Sponsor	AventaMed DAC (Industry)

**Primary outcome**

**Procedure Success**

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05741333](https://clinicaltrials.gov/study/NCT05741333)