

**K171761 ACCLARENT AERA Eustachian Tube Balloon Dilation System**Jan 16, 2018  
216 days to decisionK171761 · Product code: **PNZ** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k171761/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eustachian Tube Balloon Dilation Device (PNZ)
Date received	Jun 14, 2017
Decision date	Jan 16, 2018
Days to decision	216 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acclarent, Inc.</b>
Location	Irvine, CA, US
Contact	James Patrick Garvey II
Website	<a href="https://www.acclarent.com">https://www.acclarent.com</a>
510(k) history	45 submissions · 44 cleared · 2005-2026

Acclarent, Inc. is a subsidiary of Integra LifeSciences based in Irvine, California. The company develops technology for Ear, Nose, Throat related conditions. Acclarent has received FDA 510(k) clearances from total submissions since its first clearance in 2005. Ear, Nose, Throat devices represent the dominant focus, accounting for 76% of all submissions. The company's latest clearance was in 2026, demonstrating continued regulatory activity. The company specializes in minimally invasive surgical instruments and balloon dilation systems for sinus and Eustachian tube proced...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k171761/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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