

**K230742 ACCLARENT AERA Eustachian Tube Dilation System**Dec 13, 2023  
271 days to decisionK230742 · Product code: **PNZ** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k230742/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Eustachian Tube Balloon Dilation Device (PNZ)
Date received	Mar 17, 2023
Decision date	Dec 13, 2023
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acclarent, Inc.</b>
Location	Irvine, CA, US
Contact	Kamrie Sarnosky
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/k230742/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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