

**K161697 Acclarent NavWire Sinus Navigation Guidewire**Oct 24, 2016  
126 days to decisionK161697 · Product code: **PGW** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k161697/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Jun 20, 2016
Decision date	Oct 24, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acclarent, Inc.</b>
Location	Irvine, CA, US
Contact	ANNA HWANG
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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