

K221037 TruDi Shaver BladeJul 20, 2022
104 days to decisionK221037 · Product code: **PGW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k221037/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Apr 7, 2022
Decision date	Jul 20, 2022
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Acclarent, Inc.
Location	Irvine, CA, US
Contact	Leena Zalavadia
Website	https://www.acclarent.com
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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Device record: <https://www.510kdatabase.net/k221037/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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