FDA 510(k) Premarket Notification

CLEARED

K231862 TruDi® Navigation System V3 (FG-2000-00)

Jul 21, 2023
28 days to decision

K231862 · Product code: **PGW** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k231862/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ear, Nose, And Throat Stereotaxic Instrument (PGW)
Date received	Jun 23, 2023
Decision date	Jul 21, 2023
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acclarent, Inc.**
Location	Irvine, CA, US
Contact	Kamrie Sarnosky
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...

REGULATORY CONSULTANT

Consulting firm	**Biosense Webster (Israel) , Ltd.**
Contact	Dikla Dayan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov