FDA 510(k) Premarket Notification

K161698 Relieva UltirraNav Sinus Balloon Catheter

CLEARED

Oct 24, 2016
126 days to decision

K161698 · Product code: **LRC** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k161698/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jun 20, 2016
Decision date	Oct 24, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acclarent, Inc.**
Location	Irvine, CA, US
Contact	JAMES PATRICK GARVEY
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...