FDA 510(k) Premarket Notification

K183090 Relieva Tract Balloon Dilation System

CLEARED

Apr 19, 2019
164 days to decision

K183090 · Product code: **QGK** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k183090/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Balloon, Nasal Airway (QGK)
Date received	Nov 6, 2018
Decision date	Apr 19, 2019
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acclarent, Inc.**
Location	Irvine, CA, US
Contact	Leena Sorathia
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...