

K061903 RELIEVA SINUS BALLOON CATHETERAug 18, 2006
44 days to decisionK061903 · Product code: **LRC** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k061903/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Jul 5, 2006
Decision date	Aug 18, 2006
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acclarent, Inc.
Location	Irvine, CA, US
Contact	KERI YEN
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...
