

K143541 Relieva SpinPlus Balloon Sinuplasty SystemApr 22, 2015
128 days to decisionK143541 · Product code: **LRC** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k143541/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Dec 15, 2014
Decision date	Apr 22, 2015
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Acclarent, Inc.
Location	Irvine, CA, US
Contact	Pavan Sethi
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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