

**K052198 RELIEVA SINUS BALLOON INFLATION DEVICE**Aug 31, 2005  
19 days to decisionK052198 · Product code: **LRC** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k052198/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	Aug 12, 2005
Decision date	Aug 31, 2005
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acclarent, Inc.</b>
Location	Irvine, CA, US
Contact	SU-MIEN CHONG
Website	<a href="https://www.acclarent.com">https://www.acclarent.com</a>
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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