

K110218 INSPIRA AIR BALLOON DILATION SYSTEMMar 31, 2011
65 days to decisionK110218 · Product code: **KTI** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k110218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bronchoscope Accessory (KTI)
Date received	Jan 25, 2011
Decision date	Mar 31, 2011
Days to decision	65 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...
