FDA 510(k) Premarket Notification

K062458 ETHMOID SINUS SPACER

CLEARED

Sep 15, 2006
23 days to decision

K062458 · Product code: **KAM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k062458/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Sinus (KAM)
Date received	Aug 23, 2006
Decision date	Sep 15, 2006
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acclarent, Inc.**
Location	Irvine, CA, US
Contact	DEBBIE COGAN
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...