FDA 510(k) Premarket Notification

K012532 SEPRAGEL SINUS

CLEARED

Oct 30, 2001
85 days to decision

K012532 · Product code: **LYA** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k012532/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Splint, Intranasal Septal (LYA)
Date received	Aug 6, 2001
Decision date	Oct 30, 2001
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Genzyme Corp.**
Location	Cambridge, MA, US
Contact	NANCY A IMMEL
Website	http://www.genzyme.com
510(k) history	27 submissions · 27 cleared · 1991-2006

Genzyme Corp. was an American biotechnology company headquartered in Cambridge, Massachusetts. The company specialized in diagnostic and surgical medical devices across multiple therapeutic areas. Genzyme received FDA 510(k) clearances from total submissions between 1991 and 2006. The company's cleared devices spanned chemistry devices, microbiology diagnostics, and surgical implants including wound closure systems and bioresorbable barriers. This regulatory track record reflects the company's broad portfolio across diagnostic and surgical specialties. Genzyme was acquire...