FDA 510(k) Premarket Notification

K080956 MODIFICATION TO VF GEL PLUS

CLEARED

Apr 25, 2008
22 days to decision

K080956 · Product code: **MIX** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k080956/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Apr 3, 2008
Decision date	Apr 25, 2008
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Coapt Systems, Inc.**
Location	Palo Alto, CA, US
Contact	LINDA RUEDY
510(k) history	17 submissions · 17 cleared · 2002-2009