FDA 510(k) Premarket Notification

K050957 EUTROCHAR

CLEARED

May 18, 2005
33 days to decision

K050957 · Product code: **MDM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k050957/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Manual, Surgical, General Use (MDM)
Date received	Apr 15, 2005
Decision date	May 18, 2005
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Special Devices, Inc.**
Location	Grass Valley, CA, US
Contact	JOSEPH J SPRANZA III
510(k) history	2 submissions · 2 cleared · 1998-2005