FDA 510(k) Premarket Notification

K965080 ANSPACH MICROMAX SYSTEM

CLEARED

Jan 10, 1997
22 days to decision

K965080 · Product code: **ERL** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k965080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drill, Surgical, Ent (electric Or Pneumatic) Including Handpiece (ERL)
Date received	Dec 19, 1996
Decision date	Jan 10, 1997
Days to decision	22 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**The Anspach Effort, Inc.**
Location	Mchenry, IL, US
Contact	WILLIAM E ANSPACH, III M.D.
510(k) history	60 submissions · 60 cleared · 1980-2022