FDA 510(k) Premarket Notification

K984031 SPIROVIT, MODEL SP-250

CLEARED

Apr 30, 1999
169 days to decision

K984031 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k984031/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Nov 12, 1998
Decision date	Apr 30, 1999
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Schiller AG**
Location	Baar, CH
Contact	MARKUS BUETLER
510(k) history	16 submissions · 16 cleared · 1985-2023