FDA 510(k) Premarket Notification

K973138 SPIROCARD

CLEARED

Oct 28, 1998
433 days to decision

K973138 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k973138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Aug 21, 1997
Decision date	Oct 28, 1998
Days to decision	433 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Qrs Diagnostic, LLC**
Location	Plymouth, MN, US
Contact	KEVIN J DRISCOLL
510(k) history	7 submissions · 7 cleared · 1998-2009