FDA 510(k) Premarket Notification

K080921 SPIRO-MASTER PC-10 SPIROMETRY SYSTEM

CLEARED

Jan 21, 2009
295 days to decision

K080921 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k080921/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Apr 1, 2008
Decision date	Jan 21, 2009
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Chest M.I., Inc.**
Location	Tokyo, JP
Contact	FUMIAKI KANAI
510(k) history	2 submissions · 2 cleared · 2009-2009