

K922428 FUKUDA DENSHI MODEL SPIROSIFT SP-5000Jan 15, 1993
238 days to decisionK922428 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k922428/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	May 22, 1992
Decision date	Jan 15, 1993
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fukuda Denshi USA, Inc.
Location	Mchenry, IL, US
Contact	DAVID J GERAGHTY
510(k) history	68 submissions · 68 cleared · 1984-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k922428/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026