

K841858 SPIROLOOPJul 11, 1984
68 days to decisionK841858 · Product code: **BSE** · AnesthesiologySource: <https://www.510kdatabase.net/k841858/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Helium, Gaseous-phase (BSE)
Date received	May 4, 1984
Decision date	Jul 11, 1984
Days to decision	68 days
Third-party review	No

APPLICANT

Company	Datamed, Inc.
Location	Walker, MI, US
510(k) history	3 submissions · 3 cleared · 1981-1991

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Device record: <https://www.510kdatabase.net/k841858/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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