

K782016 SPIROCARE 108-BDec 13, 1978
8 days to decisionK782016 · Product code: **BWF** · AnesthesiologySource: <https://www.510kdatabase.net/k782016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Therapeutic (incentive) (BWF)
Date received	Dec 5, 1978
Decision date	Dec 13, 1978
Days to decision	8 days
Third-party review	No

APPLICANT

Company	Marion Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	38 submissions · 34 cleared · 1978-1989

Marion Laboratories, Inc. was a U.S. pharmaceutical company based in Kansas City, Missouri, specializing in bringing to market drugs discovered but unmarketed by other companies. The company operated from 1950 until 1996. Marion Laboratories received FDA 510(k) clearances from total submissions between 1978 and 1989. The company's cleared devices span General & Plastic Surgery, Toxicology, and Microbiology categories, reflecting a diverse regulatory portfolio during its active period. This company is now a historical record. No FDA 510(k) clearances have been issued since...

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