

K841909 VAGINAL SPECULUM - DISPOSABLEJul 31, 1984
83 days to decisionK841909 · Product code: **HIB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k841909/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	May 9, 1984
Decision date	Jul 31, 1984
Days to decision	83 days
Third-party review	No

APPLICANT

Company	Galenica Enterprises, Inc.
Location	Walker, MI, US
510(k) history	5 submissions · 5 cleared · 1984-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k841909/> 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 June 29, 2026