

K802315 UTERINE SOUNDJan 12, 1981
111 days to decisionK802315 · Product code: **HHM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k802315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sound, Uterine (HHM)
Date received	Sep 23, 1980
Decision date	Jan 12, 1981
Days to decision	111 days
Third-party review	No

APPLICANT

Company	Gynometrics, Inc.
Location	Mchenry, IL, US
510(k) history	4 submissions · 4 cleared · 1981-1981

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802315/> 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 30, 2026