

**K853640 WELLINGTON HOSPITAL PATTERN SELF RETAINING
VAGINAL**Oct 29, 1985
70 days to decisionK853640 · Product code: **HDF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k853640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Metal (HDF)
Date received	Aug 20, 1985
Decision date	Oct 29, 1985
Days to decision	70 days
Third-party review	No

APPLICANT

Company	Downs Surgical , Ltd.
Location	Mchenry, IL, US
Contact	GEOFFREY W DOWN
510(k) history	60 submissions · 60 cleared · 1980-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853640/>. 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 22, 2026