

K974228 HOSPITAL'S SPECDec 12, 1997
30 days to decisionK974228 · Product code: **HIB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k974228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Nov 12, 1997
Decision date	Dec 12, 1997
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Gps
Location	Port Washington, NY, US
Contact	LOUIS PAGLIARA
510(k) history	2 submissions · 2 cleared · 1997-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974228/> 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