

K933521 SPECULUMMar 7, 1994
230 days to decisionK933521 · Product code: **HIB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k933521/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Jul 20, 1993
Decision date	Mar 7, 1994
Days to decision	230 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bioteque America, Inc.
Location	Levittown, PA, US
Contact	DENIS DORSEY
510(k) history	10 submissions · 10 cleared · 1992-2004

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