

K973853 KOLPLAST VAGINAL SPECULUMDec 19, 1997
72 days to decisionK973853 · Product code: **HIB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k973853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Oct 8, 1997
Decision date	Dec 19, 1997
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kolplast Comercial E Industrial Ltda
Location	Crofton, MD, US
Contact	E J SMITH
510(k) history	1 submissions · 1 cleared · 1997-1997

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