

K110766 KOLPLUX SYSTEMSep 15, 2011
181 days to decisionK110766 · Product code: **HIB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k110766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Mar 18, 2011
Decision date	Sep 15, 2011
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kolplast CI Ltda
Location	Crofton, MD, US
Contact	E.J. Smith
510(k) history	1 submissions · 1 cleared · 2011-2011

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