

K060797 NAKEDApr 7, 2006
14 days to decisionK060797 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k060797/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Mar 24, 2006
Decision date	Apr 7, 2006
Days to decision	14 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Veraxis Int&apos;L, Inc.
Location	New York, NY, US
Contact	JULES T MITCHEL
510(k) history	1 submissions · 1 cleared · 2006-2006

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