

K912405 LATEX PROPHYLACTIC (CONDOM)Jul 21, 1992
418 days to decisionK912405 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k912405/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	May 30, 1991
Decision date	Jul 21, 1992
Days to decision	418 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hevealactics Intl. Sdn Bhd
Location	La Mirada, CA, US
Contact	YONG W KOO
510(k) history	2 submissions · 2 cleared · 1991-1992

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