

K113061 LARGE/EXTRA LAGRE CONDOMDec 7, 2011
54 days to decisionK113061 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k113061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Condom (HIS)
Date received	Oct 14, 2011
Decision date	Dec 7, 2011
Days to decision	54 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Karex Industries Sdn. Bhd.
Location	Pontian Kecil, Jalan Johor, MY
Contact	LAI PENG
510(k) history	8 submissions · 8 cleared · 2007-2023

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