

K012653 MALE LATEX CONDOMSep 21, 2001
39 days to decisionK012653 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k012653/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Aug 13, 2001
Decision date	Sep 21, 2001
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Qingdao Shuang Die Latex Production Co.,Ltd
Location	Durham, NC, US
Contact	ELI J CARTER
510(k) history	1 submissions · 1 cleared · 2001-2001

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