

**K081413 TWINLOTUS AND SHIELDS NATURAL RUBBER
LATEX CONDOM**Oct 24, 2008
157 days to decisionK081413 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k081413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	May 20, 2008
Decision date	Oct 24, 2008
Days to decision	157 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Dailian Latex Company, Ltd.
Location	Dailian City, Liaoning, CN
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081413/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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