FDA 510(k) Premarket Notification

K080833 LOVE GUARD MALE LATEX CONDOM

CLEARED

Aug 7, 2008
135 days to decision

K080833 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k080833/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Mar 25, 2008
Decision date	Aug 7, 2008
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tianjin Human-Care Latex Corporation**
Location	West Windsor, NJ, US
Contact	SIMON LI
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k080833/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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