

K004016 SHEER THIN AROMAS BLUE LATEX CONDOMMar 27, 2001
90 days to decisionK004016 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k004016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Dec 27, 2000
Decision date	Mar 27, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eagle Twe, Inc.
Location	Tucker, GA, US
Contact	KEITH F HEINTZ
510(k) history	5 submissions · 5 cleared · 2001-2005

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