

K010028 SHEER THIN AROMAS RED LATEX CONDOMMar 30, 2001
86 days to decisionK010028 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k010028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Jan 3, 2001
Decision date	Mar 30, 2001
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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