

K011480 VIVAMay 24, 2001
10 days to decisionK011480 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k011480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	May 14, 2001
Decision date	May 24, 2001
Days to decision	10 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Richter Rubber Technology Sdn. Bhd.
Location	Louisville, KY, US
Contact	FRANK C SADLO
510(k) history	1 submissions · 1 cleared · 2001-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026