

**K083817 M. DIOR BRAND**Sep 16, 2009  
268 days to decisionK083817 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k083817/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Dec 22, 2008
Decision date	Sep 16, 2009
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Suzhou Colour-Way Enterprise Development Co., Ltd.</b>
Location	Haidian District, Beijing, CN
Contact	CHU XIAOAN
510(k) history	2 submissions · 2 cleared · 2009-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083817/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 8, 2026