

K050360 TULIP CONDOMMar 1, 2005
15 days to decisionK050360 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k050360/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Condom (HIS) |
| Date received | Feb 14, 2005 |
| Decision date | Mar 1, 2005 |
| Days to decision | 15 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Shanghai Latex Factory |
| Location | Ramsey, NJ, US |
| Contact | LOU JI |
| 510(k) history | 3 submissions · 3 cleared · 1989-2005 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050360/> 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