

K140379 MEGA BIG BOY CONDOMJul 1, 2014
137 days to decisionK140379 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k140379/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Condom (HIS) |
| Date received | Feb 14, 2014 |
| Decision date | Jul 1, 2014 |
| Days to decision | 137 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Okamoto USA, Inc. |
| Location | Stratford, CT, US |
| Contact | JEFFREY N GIBBS |
| 510(k) history | 14 submissions · 14 cleared · 1987-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140379/> 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 May 27, 2026