

K031007 KWIKEZE MALE CONDOM APPLICATORNov 14, 2003
228 days to decisionK031007 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k031007/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Condom (HIS) |
| Date received | Mar 31, 2003 |
| Decision date | Nov 14, 2003 |
| Days to decision | 228 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Condax, LLC |
| Location | Durham, NC, US |
| Contact | ELI J CARTER |
| 510(k) history | 2 submissions · 2 cleared · 2003-2006 |

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