

K140665 GenPrime Snap-Top Split Key CupDec 8, 2014
265 days to decisionK140665 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k140665/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Barbiturate (DIS) |
| Date received | Mar 18, 2014 |
| Decision date | Dec 8, 2014 |
| Days to decision | 265 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Genprime, Inc. |
| Location | Oms River, NJ, US |
| Contact | Darby McLean |
| 510(k) history | 2 submissions · 2 cleared · 2013-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k140665/> 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 5, 2026