

K122340 PRODIGY CHOICENov 26, 2013
481 days to decisionK122340 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k122340/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Blood Glucose, Over The Counter (NBW) |
| Date received | Aug 2, 2012 |
| Decision date | Nov 26, 2013 |
| Days to decision | 481 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Prodigy Diabetes Care, LLC |
| Location | Crofton, MD, US |
| Contact | E J SMITH |
| 510(k) history | 3 submissions · 3 cleared · 2011-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122340/> 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 8, 2026