

**K053529 ONETOUCH ULTRA 2 BLOOD GLUCOSE  
MONITORING SYSTEM**Jan 17, 2006  
29 days to decisionK053529 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k053529/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Special   |
| Device classification | System, Test, Blood Glucose, Over The Counter (NBW) |
| Date received         | Dec 19, 2005  |
| Decision date         | Jan 17, 2006  |
| Days to decision      | 29 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Lifescan, Inc.</b>                   |
| Location       | Mchenry, IL, US                         |
| Contact        | LISA MCGRATH                            |
| 510(k) history | 42 submissions · 42 cleared · 1981-2013 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053529/> 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 7, 2026