

K993590 FRUCTOSAMINE REAGENT SET, CALIBRATOR, AND CONTROL SETDec 21, 1999
60 days to decisionK993590 · Product code: **LCP** · Chemistry
Source: <https://www.510kdatabase.net/k993590/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Assay, Glycosylated Hemoglobin (LCP) |
| Date received | Oct 22, 1999 |
| Decision date | Dec 21, 1999 |
| Days to decision | 60 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Pointe Scientific, Inc., |
| Location | Mchenry, IL, US |
| Contact | WILLIAM F WALTERS JR. |
| 510(k) history | 74 submissions · 74 cleared · 1981-2007 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993590/> 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 26, 2026