

K934376 STC DIAGNOSTICS AUTO-LYTE BARBITURATES EIADec 7, 1993
89 days to decisionK934376 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k934376/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Barbiturate (DIS) |
| Date received | Sep 9, 1993 |
| Decision date | Dec 7, 1993 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Solarcare, Inc. |
| Location | Bethlehem, PA, US |
| Contact | R. SAM NIEDBALA |
| 510(k) history | 6 submissions · 6 cleared · 1993-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934376/> 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 28, 2026