

**K923532 NATIONAL SCREENING INSTITUTE MICRO-PLATE  
TSH ASSAY**Mar 12, 1993  
239 days to decisionK923532 · Product code: **JLW** · Chemistry  
Source: <https://www.510kdatabase.net/k923532/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Radioimmunoassay, Thyroid-stimulating Hormone (JLW) |
| Date received         | Jul 16, 1992  |
| Decision date         | Mar 12, 1993  |
| Days to decision      | 239 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Solarcare Technologies Corp,Inc.</b> |
| Location       | Bethlehem, PA, US                       |
| Contact        | SAM NIEDBALA                            |
| 510(k) history | 28 submissions · 28 cleared · 1991-1996 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k923532/> 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 29, 2026