

**K831641 READER MICROELISA SYSTEM**Aug 11, 1983  
80 days to decisionK831641 · Product code: **LIB** · ChemistrySource: <https://www.510kdatabase.net/k831641/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, General Purpose, Microbiology, Diagnostic (LIB)
Date received	May 23, 1983
Decision date	Aug 11, 1983
Days to decision	80 days
Third-party review	No

**APPLICANT**

---

Company	<b>Organon Teknika Corp.</b>
Location	Mchenry, IL, US
510(k) history	130 submissions · 129 cleared · 1980-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k831641/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 22, 2026