

**K802939 HERPES SIMPLEX TYPE I**Dec 31, 1980  
42 days to decisionK802939 · Product code: **GON** · Microbiology  
Source: <https://www.510kdatabase.net/k802939/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Rubella (GON)
Date received	Nov 19, 1980
Decision date	Dec 31, 1980
Days to decision	42 days
Third-party review	No

**APPLICANT**

---

Company	<b>Orion Diagnostica, Inc.</b>
Location	Mchenry, IL, US
510(k) history	28 submissions · 28 cleared · 1980-1994

---

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

Device record: <https://www.510kdatabase.net/k802939/> 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 June 30, 2026