

**K801019 125I-IGE RADIOIMMUNOASSAY KIT**May 20, 1980  
20 days to decisionK801019 · Product code: **DGC** · Immunology  
Source: <https://www.510kdatabase.net/k801019/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Apr 30, 1980
Decision date	May 20, 1980
Days to decision	20 days
Third-party review	No

**APPLICANT**

---

Company	<b>Bio-Ria</b>
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1980-1981

---

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

Device record: <https://www.510kdatabase.net/k801019/> 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 July 1, 2026