

**K955363 INCSTAR HSZ I/II IGG ELISA ASSAY**Jul 24, 1996  
245 days to decisionK955363 · Product code: **IGC** · Microbiology  
Source: <https://www.510kdatabase.net/k955363/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Formalin-saline (IGC)
Date received	Nov 22, 1995
Decision date	Jul 24, 1996
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Incstar Corp.</b>
Location	Stillwater, MN, US
Contact	MARY FRICK
510(k) history	58 submissions · 57 cleared · 1987-1997

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955363/> 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 29, 2026