

**K863858 TANDEM-M IMMUNOENZYMETRIC ASSAY FOR IGE--**Nov 3, 1986  
31 days to decisionK863858 · Product code: **DGC** · Immunology  
Source: <https://www.510kdatabase.net/k863858/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Oct 3, 1986
Decision date	Nov 3, 1986
Days to decision	31 days
Third-party review	No

**APPLICANT**

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Company	<b>Hybritech, Inc.</b>
Location	Mchenry, IL, US
Contact	BRUNI, PH.D.
510(k) history	63 submissions · 63 cleared · 1981-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k863858/>; 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