

K843408 ENCORE IGE REAGENTOct 1, 1984
31 days to decisionK843408 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k843408/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Aug 31, 1984
Decision date	Oct 1, 1984
Days to decision	31 days
Third-party review	No

APPLICANT

Company	Hybritech, Inc.
Location	Mchenry, IL, US
510(k) history	63 submissions · 63 cleared · 1981-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k843408/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026