

K914959 MAGIC LITE SQ SPECIFIC IGE IMMUNOASSAY SYSTEM

Aug 20, 1992
289 days to decision

K914959 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k914959/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Nov 5, 1991
Decision date	Aug 20, 1992
Days to decision	289 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ciba Corning Diagnostics Corp.
Location	East Walpole, MA, US
Contact	WILLIAM J.PIGNATO
510(k) history	125 submissions · 125 cleared · 1986-1996

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Device record: <https://www.510kdatabase.net/k914959/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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