FDA 510(k) Premarket Notification

K934594 MAGIC LITE SQ SPECIFIC IGE IMMUNOASSAY SYSTEM

CLEARED

Apr 21, 1994
209 days to decision

K934594 · Product code: **DGC** · Immunology
Source: https://www.510kdatabase.net/k934594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Sep 24, 1993
Decision date	Apr 21, 1994
Days to decision	209 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k934594/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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