

K822677 FITC ANTISERA TO HUMAN IGMNov 17, 1982
75 days to decisionK822677 · Product code: **DFH** · Microbiology
Source: <https://www.510kdatabase.net/k822677/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kappa, Antigen, Antiserum, Control (DFH)
Date received	Sep 3, 1982
Decision date	Nov 17, 1982
Days to decision	75 days
Third-party review	No

APPLICANT

Company	Amico Lab, Inc.
Location	Mchenry, IL, US
510(k) history	32 submissions · 32 cleared · 1982-1985

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Device record: <https://www.510kdatabase.net/k822677/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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