

K832265 FITC GOAT ANTI-HUMAN IGM H CHAINOct 31, 1983
123 days to decisionK832265 · Product code: **DFT** · Immunology
Source: <https://www.510kdatabase.net/k832265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igm, Antigen, Antiserum, Control (DFT)
Date received	Jun 30, 1983
Decision date	Oct 31, 1983
Days to decision	123 days
Third-party review	No

APPLICANT

Company	Gelco Diagnostics, Inc.
Location	Mchenry, IL, US
510(k) history	14 submissions · 14 cleared · 1983-1983

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Device record: <https://www.510kdatabase.net/k832265/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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