

K990553 IGM FLEX REAGENT CARTRIDGEMar 22, 1999
28 days to decisionK990553 · Product code: **CFQ** · Immunology
Source: <https://www.510kdatabase.net/k990553/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Immunoglobulins (g, A, M) (CFQ) |
| Date received | Feb 22, 1999 |
| Decision date | Mar 22, 1999 |
| Days to decision | 28 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dade Behring, Inc. |
| Location | Newark,, DE, US |
| Contact | CATHY P CRAFT |
| 510(k) history | 343 submissions · 343 cleared · 1978-2010 |

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