

K970177 ANTI-CARDIOLIPIN ANTIBODY (ACA) SCREEN ELISAJun 11, 1997
145 days to decisionK970177 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k970177/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Anticardiolipin Immunological (MID) |
| Date received | Jan 17, 1997 |
| Decision date | Jun 11, 1997 |
| Days to decision | 145 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Immco Diagnostics, Inc. |
| Location | Buffalo, NY, US |
| Contact | RICHARD E GRECO, R.A.C. |
| 510(k) history | 55 submissions · 55 cleared · 1988-2018 |

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