

K983740 IS-ANTI-PR3 IGG ELISA TEST SYSTEMNov 18, 1998
27 days to decisionK983740 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k983740/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB) |
| Date received | Oct 22, 1998 |
| Decision date | Nov 18, 1998 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Columbia Bioscience, Inc. |
| Location | Frederick, MD, US |
| Contact | NORMAN JENKINS |
| 510(k) history | 13 submissions · 13 cleared · 1996-1999 |

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