

K963803 CENTOCOR CA 15-3 RIA MODEL NO. 800-033May 23, 1997
242 days to decisionK963803 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k963803/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Immunological, Antigen, Tumor (MOI) |
| Date received | Sep 23, 1996 |
| Decision date | May 23, 1997 |
| Days to decision | 242 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Centocor, Inc. |
| Location | Mchenry, IL, US |
| Contact | CHRISTOPHER ZALESKY |
| 510(k) history | 3 submissions · 3 cleared · 1982-1997 |

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