FDA 510(k) Premarket Notification

# K790012 RHEUMOGEN TEST SYSTEM

**CLEARED**

Jan 26, 1979
24 days to decision

K790012 · Product code: **DHR** · Immunology
Source: https://www.510kdatabase.net/k790012/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Rheumatoid Factor (DHR) |
| Date received | Jan 2, 1979 |
| Decision date | Jan 26, 1979 |
| Days to decision | 24 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Calbiochem-Behring Corp.** |
| Location | Mchenry, IL, US |
| 510(k) history | 41 submissions · 41 cleared · 1978-1983 |