

K802448 RA 80 EIKEN KIT DETERM. OF RHEUMATIC F.Jan 5, 1981
89 days to decisionK802448 · Product code: **DHR** · Immunology
Source: <https://www.510kdatabase.net/k802448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Oct 8, 1980
Decision date	Jan 5, 1981
Days to decision	89 days
Third-party review	No

APPLICANT

Company	Syn-Kit, Inc.
Location	Walker, MI, US
510(k) history	34 submissions · 34 cleared · 1980-1986

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Device record: <https://www.510kdatabase.net/k802448/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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