

K800605 ANA LATEX SLIDE TESTApr 2, 1980
16 days to decisionK800605 · Product code: **DHC** · Microbiology
Source: <https://www.510kdatabase.net/k800605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Systemic Lupus Erythematosus (DHC)
Date received	Mar 17, 1980
Decision date	Apr 2, 1980
Days to decision	16 days
Third-party review	No

APPLICANT

Company	Biologics Intl., Inc.
Location	Mchenry, IL, US
510(k) history	9 submissions · 9 cleared · 1979-1988

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Device record: <https://www.510kdatabase.net/k800605/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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