

K801098 ENZYME-IMMUNOASSAY (RUBELLA ANTIBODIES)Sep 16, 1980
130 days to decisionK801098 · Product code: **GOL** · Microbiology
Source: <https://www.510kdatabase.net/k801098/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Ha (including Ha Control), Rubella (GOL)
Date received	May 9, 1980
Decision date	Sep 16, 1980
Days to decision	130 days
Third-party review	No

APPLICANT

Company	Flow Laboratories, Inc.
Location	Mchenry, IL, US
Website	https://www.flowlabs.com
510(k) history	57 submissions · 56 cleared · 1976-1986

Flow Laboratories, Inc. is located in McHenry, US. The company specializes in laboratory and diagnostic devices. Flow Laboratories has a substantial FDA 510(k) regulatory history. The company received FDA 510(k) clearances from total submissions between 1976 and 1986. The company is inactive and maintains a historical record only, with no clearances in more than five years. Historical cleared devices span chemistry, microbiology, and pathology categories. Notable products include the UNISKAN II chemistry analyzer, TITERTEK microplate washers and microplate equipment, and ...

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