

K802937 RUBELLA VIRUS ANTIGENS & CONTROLSDec 31, 1980
42 days to decisionK802937 · Product code: **GON** · Microbiology
Source: <https://www.510kdatabase.net/k802937/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Rubella (GON)
Date received	Nov 19, 1980
Decision date	Dec 31, 1980
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Orion Diagnostica, Inc.
Location	Mchenry, IL, US
510(k) history	28 submissions · 28 cleared · 1980-1994

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Device record: <https://www.510kdatabase.net/k802937/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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