

K894262 RUBELLA ANTIGEN AND CONTROL ANTIGENOct 16, 1989
117 days to decisionK894262 · Product code: **GON** · Microbiology
Source: <https://www.510kdatabase.net/k894262/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Rubella (GON)
Date received	Jun 21, 1989
Decision date	Oct 16, 1989
Days to decision	117 days
Third-party review	No

APPLICANT

Company	Microbix Biosystems, Inc.
Location	Canada, CA
Contact	JANIS FREESTONE
510(k) history	7 submissions · 7 cleared · 1985-1989

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894262/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026