FDA 510(k) Premarket Notification

K802939 HERPES SIMPLEX TYPE I

CLEARED

Dec 31, 1980
42 days to decision

K802939 · Product code: **GON** · Microbiology
Source: https://www.510kdatabase.net/k802939/

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