

K200129 OncoMate MSI Dx Analysis SystemJul 26, 2021
552 days to decisionK200129 · Product code: **PZJ** · Pathology
Source: <https://www.510kdatabase.net/k200129/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lynch Syndrome Test System (PZJ)
Date received	Jan 21, 2020
Decision date	Jul 26, 2021
Days to decision	552 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Promega Corporation
Location	Madison, WI, US
Contact	Ron Wheeler
Website	http://www.promega.com/
510(k) history	1 submissions · 1 cleared · 2021-2021

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