FDA 510(k) Premarket Notification

CLEARED

K232286 Savanna HSV 1+2/VZV Assay, Savanna HSV 1+2/VZV Control Set, Savanna Instrument

Dec 20, 2023
141 days to decision

K232286 · Product code: **PGI** · Microbiology
Source: https://www.510kdatabase.net/k232286/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Herpes Virus (vzv, Hsv1, Hsv2), Dna Detection Assay For Cutaneous And Mucocutaneous Lesion Samples (PGI)
Date received	Aug 1, 2023
Decision date	Dec 20, 2023
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Quidel Corporation**
Location	San Diego, CA, US
Contact	Ronald Lollar
510(k) history	37 submissions · 35 cleared · 2010-2024

REGULATORY CONSULTANT

Consulting firm	**Quidelortho Corporation**
Contact	Selena Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov