

K180559 HSV 1 & 2 ELITe MGB KitOct 29, 2018
242 days to decisionK180559 · Product code: **PGI** · Microbiology
Source: <https://www.510kdatabase.net/k180559/>**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	Mar 1, 2018
Decision date	Oct 29, 2018
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ELITe InGenius

APPLICANT

Company	Elitechgroup
Location	Bothell, WA, US
Contact	Terry Trimmingham
510(k) history	17 submissions · 17 cleared · 2011-2018

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