

K192073 Helix Genetic Health Risk App for late-onset Alzheimer's diseaseDec 23, 2020
509 days to decisionK192073 · Product code: PTA · Immunology
Source: <https://www.510kdatabase.net/k192073/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Genetic Variant Detection And Health Risk Assessment System (PTA)
Date received	Aug 2, 2019
Decision date	Dec 23, 2020
Days to decision	509 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Helix Opco, LLC
Location	Toronto, CA
Contact	Gloria Lee
510(k) history	2 submissions · 1 cleared · 2020-2020

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