

K203626 SureStrip Vitrification Straw, SureLock Vitrification StrawJun 4, 2021
175 days to decisionK203626 · Product code: **MQK** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k203626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Labware, Assisted Reproduction (MQK)
Date received	Dec 11, 2020
Decision date	Jun 4, 2021
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Allwin Medical Devices, Inc.
Location	Anaheim, CA, US
Contact	Digish Mehta
510(k) history	7 submissions · 6 cleared · 2019-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203626/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026