

K190590 Allwin Ovum Pickup Needles (ACE Single Lumen Ovum Pickup Needle, OVUMPICK Double Lumen Ovum Pickup Needle, ACE-FL Single Lumen Ovum Pickup Needle with Flushing Line, ACE-M Manual Single Lumen Ovum Pickup Needle)Nov 25, 2019
263 days to decisionK190590 · Product code: **MQE** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k190590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Assisted Reproduction (MQE)
Date received	Mar 7, 2019
Decision date	Nov 25, 2019
Days to decision	263 days
Third-party review	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

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