

K190522 Allwin Intra Uterine Insemination Catheters (INSEMINA and INSEMINA Open Tip Intra Uterine Insemination Catheter, CURVED and CURVED Open Tip Intra Uterine Insemination Catheter, TRACKABLE and TRACKABLE Open Tip Intra Uterine Insemination Catheter, FLEXI and FLEXI Open Tip Intra Uterine Insemination Catheter, STUMPY Intra Uterine Insemination Catheter)Nov 14, 2019
255 days to decisionK190522 · Product code: **MQF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k190522/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Assisted Reproduction (MQF)
Date received	Mar 4, 2019
Decision date	Nov 14, 2019
Days to decision	255 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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