

K191138 AeroForm Tissue Expander, SmoothJul 11, 2019
72 days to decisionK191138 · Product code: **PQN** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Carbon Dioxide Gas Controlled Tissue Expander (PQN)
Date received	Apr 30, 2019
Decision date	Jul 11, 2019
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Airxpanders, Inc.
Location	Palo Alto, CA, US
Contact	Belinda Pinedo
510(k) history	3 submissions · 2 cleared · 2016-2019

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