

K210782 Tablo CartridgeNov 26, 2021
255 days to decisionK210782 · Product code: **FJK** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k210782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Tubing, Blood, With And Without Anti-regurgitation Valve (FJK)
Date received	Mar 16, 2021
Decision date	Nov 26, 2021
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Outset Medical, Inc.
Location	San Jose, CA, US
Contact	Jennifer Mascioli-Tudor
510(k) history	9 submissions · 9 cleared · 2016-2026

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