

K182895 Wilson-Cook Achalasia BalloonJan 25, 2019
102 days to decisionK182895 · Product code: **PID** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k182895/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal Dilator Balloon With Or Without Electrode Sensors (PID)
Date received	Oct 15, 2018
Decision date	Jan 25, 2019
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wilson-Cook Medical, Inc.
Location	Winstrom-Salem, NC, US
Contact	Theresa de Prat
510(k) history	125 submissions · 118 cleared · 1985-2026

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