

K172128 EsoFLIP® ES-310 Balloon CatheterNov 22, 2017
131 days to decisionK172128 · Product code: **PIE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Esophageal Dilator With Balloon And Electrode Sensors (PIE)
Date received	Jul 14, 2017
Decision date	Nov 22, 2017
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Crospon, Ltd.
Location	Bonita Springs, FL, US
Contact	John O'Dea
510(k) history	12 submissions · 12 cleared · 2009-2019

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