

K191330 Arc EnterocuffJan 31, 2020
260 days to decisionK191330 · Product code: **FDA** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k191330/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enteroscope And Accessories (FDA)
Date received	May 16, 2019
Decision date	Jan 31, 2020
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Boddingtons Plastics, Ltd.
Location	Tonbridge, Kent, GB
Contact	Shimaa Elsayy
510(k) history	5 submissions · 5 cleared · 2012-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191330/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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