FDA 510(k) Premarket Notification

K191330 Arc Enterocuff

CLEARED

Jan 31, 2020
260 days to decision

K191330 · Product code: **FDA** · Gastroenterology & Urology
Source: 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 Elsawy
510(k) history	5 submissions · 5 cleared · 2012-2020