

K162205 Arc EndoCuff and Arc EndoCuff VisionDec 9, 2016
126 days to decisionK162205 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k162205/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Aug 5, 2016
Decision date	Dec 9, 2016
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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