

K191011 Scope ProTech

May 7, 2019
21 days to decision

K191011 · Product code: **OCU** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191011/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Storage Cover (OCU)
Date received	Apr 16, 2019
Decision date	May 7, 2019
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meditech Endoscopy, Ltd.
Location	Basildon, GB
Contact	Peter Ramsey
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Accelerated Device Approval Services
Contact	Rafael Aguila

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
