

K181457 EndoStream(TM)Jul 11, 2019
402 days to decisionK181457 · Product code: **OCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181457/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Irrigation/suction System (OCX) |
| Date received | Jun 4, 2018 |
| Decision date | Jul 11, 2019 |
| Days to decision | 402 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Partnership Medical Limited |
| Location | Fenton, GB |
| Contact | Rob Hartley |
| 510(k) history | 2 submissions · 2 cleared · 2019-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------------|
| Consulting firm | Qrc Consulting, LLC |
| Contact | Silbiano Gonzales |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181457/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026