FDA 510(k) Premarket Notification

**CLEARED**

# K181127 EndoRotor Console, EndoRotor Catheters, EndoRotor Specimen Trap, EndoRotor Filter Set, EndoRotor Foot Control

Jan 3, 2019
248 days to decision

K181127 · Product code: **PTE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k181127/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Morcellator Gastroenterology (PTE) |
| Date received | Apr 30, 2018 |
| Decision date | Jan 3, 2019 |
| Days to decision | 248 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Interscope, Inc.** |
| Location | Worchester, MA, US |
| Contact | Jeffery Ryan |
| 510(k) history | 4 submissions · 3 cleared · 2017-2020 |

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Icon Clinical Research, LLC** |
| Contact | Cynthia Nolte |

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