# K211068 PrevisEA Device

**CLEARED**

Aug 4, 2021
114 days to decision

K211068 · Product code: **DQD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k211068/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stethoscope, Electronic (DQD) |
| Date received | Apr 12, 2021 |
| Decision date | Aug 4, 2021 |
| Days to decision | 114 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Entac Medical, Inc.** |
| Location | Memphis, TN, US |
| Contact | Buddy Lyons |
| 510(k) history | 2 submissions · 2 cleared · 2021-2023 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Target Health, LLC** |
| Contact | Adam Harris |

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

## CLINICAL EVIDENCE - NCT03505476

### Optimizing the Previs Device for Prediction of Postoperative Ileus

| | |
|---|---|
| Status | Completed |
| Enrollment | 203 patients (actual) |
| Study sites | 1 site |
| Condition studied | Ileus |
| Primary purpose | Diagnostic |
| Study type | Interventional |
| Study design | Single group |
| Masking | Open label |
| Completion date | Jun 5, 2023 |
| Sponsor | Jennifer Hrabe (Other) |

**Primary outcome**

Device Sensitivity for Predicting Ileus.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03505476