FDA 510(k) Premarket Notification

# K133826 INTONEMV

**CLEARED**

Jan 6, 2014
20 days to decision

K133826 · Product code: **KPI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k133826/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Stimulator, Electrical, Non-implantable, For Incontinence (KPI) |
| Date received | Dec 17, 2013 |
| Decision date | Jan 6, 2014 |
| Days to decision | 20 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Incontrol Medical, LLC** |
| Location | Brookfield, WI, US |
| Contact | JESSICA ANDRESHAK |
| 510(k) history | 7 submissions · 6 cleared · 2012-2019 |