FDA 510(k) Premarket Notification

**CLEARED**

# K192302 Mahurkar Acute Single Lumen Catheter, Mahurkar Acute Dual Lumen Catheter, Mahurkar Acute Triple Lumen Catheter, Mahurkar Acute High Pressure Triple Lumen Catheter

Jan 17, 2020
147 days to decision

K192302 · Product code: **MPB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k192302/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent - KD |
| Submission type | Traditional |
| Device classification | Catheter, Hemodialysis, Non-implanted (MPB) |
| Date received | Aug 23, 2019 |
| Decision date | Jan 17, 2020 |
| Days to decision | 147 days |
| Third-party review | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Covidien, LLC** |
| Location | Mansfield, MA, US |
| Contact | Carol S Ming |
| 510(k) history | 88 submissions · 85 cleared · 2010-2026 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k192302/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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