FDA 510(k) Premarket Notification

# K935198 GASTROENTEROLOGY AND UROLOGY GUIDEWIRE MODIFICATIONS

**CLEARED**

Sep 28, 1994
336 days to decision

K935198 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k935198/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tubes, Gastrointestinal (and Accessories) (KNT) |
| Date received | Oct 27, 1993 |
| Decision date | Sep 28, 1994 |
| Days to decision | 336 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Lake Region Mfg., Inc.** |
| Location | Mchenry, IL, US |
| Contact | CARL BEAURLINE |
| 510(k) history | 42 submissions · 42 cleared · 1977-2010 |