FDA 510(k) Premarket Notification

# K011080 BRIDGE SE SELF-EXPANDING STENT DELIVERY SYSTEM

**CLEARED**

Oct 11, 2001
185 days to decision

K011080 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k011080/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent - U |
| Submission type | Traditional |
| Device classification | Stents, Drains And Dilators For The Biliary Ducts (FGE) |
| Date received | Apr 9, 2001 |
| Decision date | Oct 11, 2001 |
| Days to decision | 185 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medtronic Ave, Inc.** |
| Location | Santa Rosa, CA, US |
| Contact | JOHN RIOLO |
| 510(k) history | 13 submissions · 2 cleared · 1999-2003 |