FDA 510(k) Premarket Notification

# K903606 GUIDEWIRE TORQUE DEVICE AND GUIDEWIRE INTRODUCER

**CLEARED**

Sep 27, 1990
59 days to decision

K903606 · Product code: **LIT** · Cardiovascular
Source: https://www.510kdatabase.net/k903606/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Jul 30, 1990 |
| Decision date | Sep 27, 1990 |
| Days to decision | 59 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **North American Instrument Corp.** |
| Location | Walker, MI, US |
| Contact | ROBERT E FRANKLIN |
| 510(k) history | 28 submissions · 28 cleared · 1983-1996 |