FDA 510(k) Premarket Notification

# K801031 BLADE SEPTOSTOMY CATHETER

**CLEARED**

Jul 28, 1980
88 days to decision

K801031 · Product code: **DXF** · Cardiovascular
Source: https://www.510kdatabase.net/k801031/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Septostomy (DXF) |
| Date received | May 1, 1980 |
| Decision date | Jul 28, 1980 |
| Days to decision | 88 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Cook, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 190 submissions · 179 cleared · 1976-2015 |