FDA 510(k) Premarket Notification

# K972570 HEARTPORT INTRODUCER SHEATH

**CLEARED**

Oct 1, 1997
83 days to decision

K972570 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k972570/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Jul 10, 1997 |
| Decision date | Oct 1, 1997 |
| Days to decision | 83 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Heartport, Inc.** |
| Location | Redwood City, CA, US |
| Contact | MARIANNE C DRENNAN |
| 510(k) history | 24 submissions · 24 cleared · 1996-2000 |