FDA 510(k) Premarket Notification

**CLEARED**

# K031398 IS-1 HEMOSTASIS VALVE, MODEL 6799

May 20, 2003
15 days to decision

K031398 · Product code: **DTL** · Cardiovascular
Source: https://www.510kdatabase.net/k031398/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL) |
| Date received | May 5, 2003 |
| Decision date | May 20, 2003 |
| Days to decision | 15 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **Guidant Corp.** |
| Location | Santa Clara, CA, US |
| Contact | Colleen McCarter Bloom |
| 510(k) history | 71 submissions · 56 cleared · 1997-2006 |

Guidant Corp. is a medical device manufacturer specializing in cardiovascular devices and surgical products. Headquartered in Indianapolis, Indiana, the company designs and manufactures artificial cardiac pacemakers, implantable cardioverter-defibrillators, stents, and related cardiovascular medical products. Guidant received FDA 510(k) clearances from total submissions between 1997 and 2006. The company's regulatory portfolio is dominated by cardiovascular devices, including guide wires, embolic protection systems, stents, and hemostasis valves. The company also cleared ...

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k031398/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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