

K944214 BAXTER HANDLE MODEL 1150Feb 10, 1995
165 days to decisionK944214 · Product code: **DTJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k944214/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Holder, Heart-valve, Prosthesis (DTJ) |
| Date received | Aug 29, 1994 |
| Decision date | Feb 10, 1995 |
| Days to decision | 165 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Baxter Edwards |
| Location | Irvine, CA, US |
| Contact | EASTER SALTZ |
| 510(k) history | 11 submissions · 10 cleared · 1993-2000 |

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