

**K954604 ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM
ROTABLATOR SYSTEM'S GUIDE WIRE LINE**Jan 18, 1996
106 days to decisionK954604 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k954604/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Peripheral, Atherectomy (MCW) |
| Date received | Oct 4, 1995 |
| Decision date | Jan 18, 1996 |
| Days to decision | 106 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | HTI FLOPPY |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Heart Technology Mfg., Inc. |
| Location | Redmond, WA, US |
| Contact | DIANE JOHNSON |
| 510(k) history | 3 submissions · 3 cleared · 1995-1996 |

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