

K945963 THE OMNIGUIDE GUIDING CATHETER WITH BALLOONFeb 8, 1995
63 days to decisionK945963 · Product code: **DQT** · Cardiovascular
Source: <https://www.510kdatabase.net/k945963/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Occluder, Catheter Tip (DQT) |
| Date received | Dec 7, 1994 |
| Decision date | Feb 8, 1995 |
| Days to decision | 63 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Micro Interventional Systems, Inc. |
| Location | Sunnyvale, CA, US |
| Contact | MARIA CARRILLO |
| 510(k) history | 1 submissions · 1 cleared · 1995-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945963/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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