

K001578 ANGIODYNAMICS SOFT-VU HYDROPHILIC COATED ANGIOGRAPHIC CATHETEROct 13, 2000
144 days to decisionK001578 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k001578/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Intravascular, Diagnostic (DQO) |
| Date received | May 22, 2000 |
| Decision date | Oct 13, 2000 |
| Days to decision | 144 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | AngioDynamics, Inc. |
| Location | Glens Falls, NY, US |
| Contact | TERI JUCKETT |
| Website | http://www.angiodynamics.com/ |
| 510(k) history | 87 submissions · 82 cleared · 1995-2025 |

AngioDynamics, Inc. is a global leader in vascular and oncology medical technologies, with a manufacturing facility in Glens Falls, US. The company develops advanced devices addressing blood flow restoration, cancer therapies, vascular access, and varicose vein treatment. AngioDynamics has received FDA 510(k) clearances from total submissions since its first clearance in 1995. The company specializes in cardiovascular devices, with recent cleared products including mechanical aspiration systems, infusion systems, and angiographic catheters. The latest FDA 510(k) clearance...

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Device record: <https://www.510kdatabase.net/k001578/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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