

K163141 NAMIC ClearaCIL Contrast Injection LinesJan 6, 2017
58 days to decisionK163141 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k163141/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intravascular, Diagnostic (DQO) |
| Date received | Nov 9, 2016 |
| Decision date | Jan 6, 2017 |
| Days to decision | 58 days |
| Third-party review | No |
| Summary / Statement | Summary |

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...
