

**K845037 PERCUTANEOUS ANGIOGRAPHIC NEEDLES**Jun 21, 1985  
176 days to decisionK845037 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k845037/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Introducer, Catheter (DYB)         |
| Date received         | Dec 27, 1984                       |
| Decision date         | Jun 21, 1985                       |
| Days to decision      | 176 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Mallinckrodt Critical Care</b>                                       |
| Location       | Mchenry, IL, US   |
| Contact        | THOMAS W TUSING   |
| Website        | <a href="https://www.mallinckrodt.com">https://www.mallinckrodt.com</a> |
| 510(k) history | 92 submissions · 92 cleared · 1976-1989                                 |

Mallinckrodt Critical Care is a medical device manufacturer based in McHenry, US. Now part of Mallinckrodt plc following a 2025 merger and subsequent restructuring, the company maintains a significant historical regulatory record in critical care and specialty medical devices. The company received FDA 510(k) clearances from total submissions between 1976 and 1989. Device clearances span anesthesiology, cardiovascular, gastroenterology, and general hospital categories. Notable cleared products include tracheal tubes, temperature monitoring systems, catheters, and related c...

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