

K173879 MiniMed Mio Advance infusion setMar 5, 2018
74 days to decisionK173879 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k173879/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Dec 21, 2017 |
| Decision date | Mar 5, 2018 |
| Days to decision | 74 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Unomedical A/S |
| Location | Roskilde, DK |
| Contact | Heidi Bjerre Lovkvist |
| 510(k) history | 13 submissions · 13 cleared · 2003-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k173879/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026