

K160648 MiniMed Quick-Set® MiniMed Sure-T® MiniMed Silhouette® MiniMed Mio®Aug 10, 2016
156 days to decisionK160648 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k160648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Mar 7, 2016
Decision date	Aug 10, 2016
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Unomedical A/S
Location	Roskilde, DK
Contact	John M Lindskog
510(k) history	13 submissions · 13 cleared · 2003-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160648/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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