

**K162812 Unomedical Comfort Subcutaneous Infusion Set,  
Unomedical Comfort Short Subcutaneous Infusion Set,  
Unomedical Neria Soft Subcutaneous Infusion Set, Medtronic  
Silhouette Subcutaneous Infusion Set, Medtronic Silhouette  
Paradigm Subcutaneous Infusion Set, Roche Accu-Chek  
Tender Subcutaneous Infusion Set, Asante Comfort  
Subcutaneous Infusion Set, Abbott Comfort Subcutaneous  
Infusion Set**

Nov 1, 2017  
391 days to decision

K162812 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k162812/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Oct 6, 2016
Decision date	Nov 1, 2017
Days to decision	391 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k162812/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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