

K192647 neria guard Infusion SetDec 13, 2019
80 days to decisionK192647 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k192647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 24, 2019
Decision date	Dec 13, 2019
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Unomedical A/S
Location	Roskilde, DK
Contact	Mette Busk Henningsen
510(k) history	13 submissions · 13 cleared · 2003-2021

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