

K211649 PCEA Syringe SetNov 23, 2021
179 days to decisionK211649 · Product code: **PWH** · General Hospital
Source: <https://www.510kdatabase.net/k211649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Administrations Sets With Neuraxial Connectors (PWH)
Date received	May 28, 2021
Decision date	Nov 23, 2021
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Baxter Healthcare Corporation
Location	Round Lake, IL, US
Contact	Jeffrey E Thompson
510(k) history	61 submissions · 60 cleared · 2004-2025

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