

**K213442 Extroducer Infusion Catheter System**Jun 10, 2022  
228 days to decisionK213442 · Product code: **KRA** · CardiovascularSource: <https://www.510kdatabase.net/k213442/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Continuous Flush (KRA)
Date received	Oct 25, 2021
Decision date	Jun 10, 2022
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SmartWise Sweden AB</b>
Location	Tullinge, SE
Contact	Maria Nordlinder
510(k) history	1 submissions · 1 cleared · 2022-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213442/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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