

**K210681 SiteSeal SV**Apr 6, 2021  
29 days to decisionK210681 · Product code: **DXC** · CardiovascularSource: <https://www.510kdatabase.net/k210681/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Clamp, Vascular (DXC)
Date received	Mar 8, 2021
Decision date	Apr 6, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ensite Vascular</b>
Location	Olathe, KS, US
Contact	Thomas Reidy
510(k) history	2 submissions · 2 cleared · 2019-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Brosseau Consulting, LLC</b>
Contact	Bryan Brosseau

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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