

K192413 SiteSeal Femoral Compression DeviceMar 31, 2020
209 days to decisionK192413 · Product code: **DXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k192413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Vascular (DXC)
Date received	Sep 4, 2019
Decision date	Mar 31, 2020
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ensite Vacular, LLC
Location	Olathe, KS, US
Contact	Tom Reidy
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	TAMM Net, Inc.
Contact	Shree Koushik

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192413/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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