

K200720 D-Stat Radial Topical HemostatJun 26, 2020
99 days to decisionK200720 · Product code: **QSX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k200720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Hemostatic Wound Dressing With Thrombin Or Other Biologics (QSX)
Date received	Mar 19, 2020
Decision date	Jun 26, 2020
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vascular Solutions, LLC
Location	Maple Grove, MN, US
Contact	Iroquois Ledbeter
Website	http://vasc.com/
510(k) history	11 submissions · 11 cleared · 2019-2024

Vascular Solutions, LLC is an interventional medical device company now part of Teleflex. The company specializes in cardiovascular devices for coronary and peripheral interventions, structural heart procedures, and mechanical circulatory support. Vascular Solutions operates with a manufacturing facility in Maple Grove, Minnesota. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2019. Cardiovascular devices represent 91% of its regulatory submissions. The latest clearance was in 2024, demonstrating continued product innova...

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