

K190012 OMNI-STAT Vascular (Rapid)Dec 18, 2019
349 days to decisionK190012 · Product code: **QSY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k190012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Wound Dressing Without Thrombin Or Other Biologics (QSY)
Date received	Jan 3, 2019
Decision date	Dec 18, 2019
Days to decision	349 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CELOX Vascular Rapid

APPLICANT

Company	Medtrade Product, Ltd.
Location	Crewe, GB
Contact	Mina Patel
510(k) history	1 submissions · 1 cleared · 2019-2019

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