

K120480 GORE(R) EMBOLIC FILTERMar 16, 2012
29 days to decisionK120480 · Product code: **NTE** · Cardiovascular
Source: <https://www.510kdatabase.net/k120480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Feb 16, 2012
Decision date	Mar 16, 2012
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates
Location	Flagstaff, AZ, US
Contact	MICHELLE ANN WELLS
Website	http://www.gore.com/
510(k) history	3 submissions · 3 cleared · 2005-2012

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