

**K081549 RX ACCUNET LP EMBOLIC PROTECTION SYSTEM**Aug 19, 2008  
77 days to decisionK081549 · Product code: **NTE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k081549/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporary Carotid Catheter For Embolic Capture (NTE)
Date received	Jun 3, 2008
Decision date	Aug 19, 2008
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Laboratories</b>
Location	Abbott Park, IL, US
Contact	VIRGINIA SINGER
Website	<a href="http://www.abbott.com">http://www.abbott.com</a>
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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