

**K191378 0.9% Sodium Chloride Injection, USP, Pre-filled COP Syringe**Sep 15, 2019  
115 days to decisionK191378 · Product code: **NGT** · General Hospital  
Source: <https://www.510kdatabase.net/k191378/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saline, Vascular Access Flush (NGT)
Date received	May 23, 2019
Decision date	Sep 15, 2019
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Medline Industries, Inc.</b>
Location	Mchenry, IL, US
Contact	Stephanie Augsburg
510(k) history	238 submissions · 234 cleared · 1977-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191378/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026