

**K231363 Hantech Pre-filled 0.9% Normal Saline Flush Syringes
(Models PFS-1003, PFS-1005, PFS-1010)**Sep 27, 2023
139 days to decisionK231363 · Product code: **NGT** · General Hospital
Source: <https://www.510kdatabase.net/k231363/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saline, Vascular Access Flush (NGT)
Date received	May 11, 2023
Decision date	Sep 27, 2023
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hantech Medical Device Co., Ltd.
Location	Ningbo, CN
Contact	Arnold Yang
510(k) history	5 submissions · 5 cleared · 2022-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231363/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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