

K214080 PentaflushJul 20, 2022
205 days to decisionK214080 · Product code: **NGT** · General Hospital
Source: <https://www.510kdatabase.net/k214080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saline, Vascular Access Flush (NGT)
Date received	Dec 27, 2021
Decision date	Jul 20, 2022
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pentaferte Italia S.R.L.
Location	Campli, IT
Contact	Rosa Di Gioia
510(k) history	3 submissions · 3 cleared · 2017-2022

REGULATORY CONSULTANT

Consulting firm	Pqe US
Contact	Luca Giustini

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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