FDA 510(k) Premarket Notification

K214080 Pentaflush

CLEARED

Jul 20, 2022
205 days to decision

K214080 · 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