

K220856 Vial Adapter Ø13mmJun 21, 2022
90 days to decisionK220856 · Product code: LHI · General Hospital
Source: <https://www.510kdatabase.net/k220856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Mar 23, 2022
Decision date	Jun 21, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avenir Performance Europeenne Medical (Apem)
Location	Châteauneuf-Landon, FR
Contact	Bruno Bertholet
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Registrar Corp.
Contact	David Lennarz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220856/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026