

K190149 Vial Adapter Ø20 mmOct 15, 2019
259 days to decisionK190149 · Product code: LHI · General Hospital
Source: <https://www.510kdatabase.net/k190149/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Jan 29, 2019
Decision date	Oct 15, 2019
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avenir Performance Europeenne Medical (Apem)
Location	Ch?teau-Landon, FR
Contact	Fatoumata Dao
510(k) history	2 submissions · 2 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Technology Sciences Group, Inc.
Contact	Om V. Singh

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

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