

**K190816 Vial Adapter Ø20 mm , Vial Adapter Ø13 mm**Nov 19, 2019  
235 days to decisionK190816 · Product code: LHI · General Hospital  
Source: <https://www.510kdatabase.net/k190816/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Mar 29, 2019
Decision date	Nov 19, 2019
Days to decision	235 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Technology Sciences Group, Inc.</b>
Contact	Om V. Singh

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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190816/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026