

K243404 HyHub™ and HyHub™ Duo Vial Access DevicesJul 18, 2025
259 days to decision

K243404 · Product code: LHI · General Hospital

Source: <https://www.510kdatabase.net/k243404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Nov 1, 2024
Decision date	Jul 18, 2025
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Takeda Pharmaceuticals
Location	Cambridge, MA, US
Contact	Louwanna Wilson
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243404/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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