

K251411 Chemfort Female Luer Lock AdaptorAug 5, 2025
90 days to decisionK251411 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k251411/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB) |
| Date received | May 7, 2025 |
| Decision date | Aug 5, 2025 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Simplivia Healthcare , Ltd. |
| Location | Kiryat Shmona, IL |
| Contact | Shay Shaham |
| 510(k) history | 6 submissions · 6 cleared · 2020-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251411/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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