

K210707 OnGuard2 Chemfort Closed Administration (CADM)Sep 23, 2021
197 days to decisionK210707 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k210707/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Mar 10, 2021
Decision date	Sep 23, 2021
Days to decision	197 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/k210707/> 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 26, 2026