

K201142 TEVADAPTOR Bag Adaptor LL, TEVADAPTOR Bag Adaptor LL with ULTRASITE, TEVADAPTOR Bag Adaptor SP with ULTRASITE, TEVADAPTOR IV Secondary Safety Set with ULTRASITE, TEVADAPTOR IV Secondary Safety set

Feb 25, 2021
302 days to decision

K201142 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k201142/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Apr 29, 2020
Decision date	Feb 25, 2021
Days to decision	302 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.net

Device record: <https://www.510kdatabase.net/k201142/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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