

K150219 Equashield Closed System drug Transfer Device (CSTD)Nov 5, 2015
279 days to decisionK150219 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k150219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Jan 30, 2015
Decision date	Nov 5, 2015
Days to decision	279 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Equashield Medical , Ltd.
Location	Migdal, IL
Contact	Raymond J Kelly
510(k) history	5 submissions · 5 cleared · 2010-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150219/>; 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 27, 2026