

K180489 TEVADAPTOR Closed Drug Reconstitution and Transfer SystemSep 21, 2018
210 days to decisionK180489 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k180489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Feb 23, 2018
Decision date	Sep 21, 2018
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Teva Medical Ltd., Migada Plant
Location	Rome, IT
Contact	Nadav Reuben
510(k) history	4 submissions · 4 cleared · 2014-2018

REGULATORY CONSULTANT

Consulting firm	Donawa Lifescience Consulting
Contact	Roger Gray

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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