

K201460 Closed System Transfer DeviceNov 23, 2022
904 days to decisionK201460 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k201460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Jun 2, 2020
Decision date	Nov 23, 2022
Days to decision	904 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shinva Ande Healthcare Apparatus Co., Ltd.
Location	Zibo, CN
Contact	XiaoLei Tian
510(k) history	6 submissions · 6 cleared · 2017-2022

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201460/> 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 25, 2026