

K173477 ChemoCLAVE Cytotoxic Medication Preparation and Delivery SystemAug 31, 2018
291 days to decisionK173477 · Product code: **ONB** · General Hospital
Source: <https://www.510kdatabase.net/k173477/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Closed Antineoplastic And Hazardous Drug Reconstitution And Transfer System (ONB)
Date received	Nov 13, 2017
Decision date	Aug 31, 2018
Days to decision	291 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Icu Medical, Inc.
Location	Walker, MI, US
Contact	Catherine E. Kang
510(k) history	66 submissions · 65 cleared · 1984-2026

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