

**K081361 CHEMOCLAVE CYTOTOXIC MEDICATION
PREPARATION AND DELIVERY SYSTEM, MODEL, CH-XXXX**Aug 28, 2008
105 days to decisionK081361 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k081361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 15, 2008
Decision date	Aug 28, 2008
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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