

**K121919 SURGICAL DRAPE WITH AAMI LIQUID BARRIER
LEVEL IV**Feb 14, 2013
227 days to decisionK121919 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k121919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Jul 2, 2012
Decision date	Feb 14, 2013
Days to decision	227 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exact Medical Manufacturing, Inc.
Location	Buffalo, NY, US
Contact	ROBERT O DEAN
510(k) history	7 submissions · 7 cleared · 2010-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121919/> 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 June 9, 2026