

K101689 EMM EQUIPMENT COVER-POLYTHYLENESep 20, 2010
96 days to decisionK101689 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k101689/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Jun 16, 2010
Decision date	Sep 20, 2010
Days to decision	96 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

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