FDA 510(k) Premarket Notification

K163556 MediClear PreOp

CLEARED

Sep 14, 2017
269 days to decision

K163556 · Product code: **KKX** · General Hospital
Source: https://www.510kdatabase.net/k163556/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	Dec 19, 2016
Decision date	Sep 14, 2017
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Covalontechnologies, Inc.**
Location	Largo, FL, US
Contact	KIM CROOKS
510(k) history	6 submissions · 6 cleared · 2005-2017