FDA 510(k) Premarket Notification

K133097 E-Z LINK

CLEARED

Mar 13, 2014
164 days to decision

K133097 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k133097/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, I.v. Fluid Transfer (LHI)
Date received	Sep 30, 2013
Decision date	Mar 13, 2014
Days to decision	164 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Duoject Medical Systems, Inc.**
Location	Bromont, Qc., CA
Contact	MARIE-CHRISTINE MESSIER
510(k) history	3 submissions · 3 cleared · 2001-2014