FDA 510(k) Premarket Notification

K140620 SPORVIEW PLUS BI TEST PACK

CLEARED

Aug 7, 2014
149 days to decision

K140620 · Product code: **FRC** · General Hospital
Source: https://www.510kdatabase.net/k140620/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Mar 11, 2014
Decision date	Aug 7, 2014
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Crosstex International**
Location	Minneapolis, MN, US
Contact	MICHAEL G NOLAN
510(k) history	4 submissions · 4 cleared · 2008-2014

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k140620/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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