

K162613 Integrated Catch-up Freedom Syringe Driver Infusion System

Aug 31, 2017
346 days to decision

K162613 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k162613/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Sep 19, 2016
Decision date	Aug 31, 2017
Days to decision	346 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Repro-Med Systems, Inc. Dba Rms Medical Products
Location	New York, NY, US
Contact	Fred Ma
510(k) history	3 submissions · 3 cleared · 2013-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k162613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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