

K201634 RG 3ml Medication CartridgeMar 26, 2021
283 days to decisionK201634 · Product code: **MRZ** · General Hospital
Source: <https://www.510kdatabase.net/k201634/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Pump, Infusion (MRZ)
Date received	Jun 16, 2020
Decision date	Mar 26, 2021
Days to decision	283 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chengdu Shifeng Medical Technology Co., Ltd.
Location	Jinhua Town, Xinjin County, CN
Contact	Nick Wang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	O&apos;Connell Regulatory Consultants, Inc.
Contact	Maureen O'Connell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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