

K181374 NRFit SyringeDec 14, 2018
204 days to decisionK181374 · Product code: **QEH** · General Hospital
Source: <https://www.510kdatabase.net/k181374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Piston Syringe With Neuraxial Connector – Epidural, Peripheral, And/or Indirect Cerebral Spinal Fluid Contact (QEH)
Date received	May 24, 2018
Decision date	Dec 14, 2018
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Caina Medical Co.,Ltd
Location	Jiangyin, CN
Contact	Jun Lu
510(k) history	21 submissions · 21 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181374/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026