

K190494 Infant IncubatorNov 25, 2019
270 days to decisionK190494 · Product code: **FMZ** · General Hospital
Source: <https://www.510kdatabase.net/k190494/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Incubator, Neonatal (FMZ)
Date received	Feb 28, 2019
Decision date	Nov 25, 2019
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo David Medical Device Co., Ltd.
Location	Ningbo, CN
Contact	Lin Dingyu
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190494/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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