FDA 510(k) Premarket Notification

K182859 Babyleo TN500

CLEARED

Feb 22, 2019
134 days to decision

K182859 · Product code: **FMZ** · General Hospital
Source: https://www.510kdatabase.net/k182859/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Incubator, Neonatal (FMZ)
Date received	Oct 11, 2018
Decision date	Feb 22, 2019
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dragerwerk AG & CO Kgaa**
Location	L?beck, DE
Contact	Dr. Bettina Mobius
510(k) history	2 submissions · 2 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Draeger Medical Sytems, Inc.**
Contact	Gale Winarsky

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