

K221603 Kangaroo OMNI™ Enteral Feeding Pump (385400)Dec 20, 2022
201 days to decisionK221603 · Product code: **LZH** · General Hospital
Source: <https://www.510kdatabase.net/k221603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion, Enteral (LZH)
Date received	Jun 2, 2022
Decision date	Dec 20, 2022
Days to decision	201 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Kangaroo OMNI™ Feeding Set 500ml (B5FD);Kangaroo OMNI™ ENTelliSet 500ml (E5FD);Kangaroo OMNI™ Feeding Set 1000ml (B10FD);Kangaroo OMNI™ ENTelliSet 1000ml (E10FD);Kangaroo OMNI™ ENPlus Spike Set (BSPFD);Kangaroo OMNI™ ENTelliSet ENPlus Spike (ESPFD);Kangaroo OMNI™ Feeding Set 500ml with Flush Bag (B5FF);Kangaroo OMNI™ ENTelliSet 500ml with Flush Bag (E5FF);Kangaroo OMNI™ Feeding Set 1000ml with Flush Bag (E10FF);Kangaroo OMNI™

APPLICANT

Company	Cardinal Health, LLC
Location	Waukegan, IL, US
Contact	Varela Fredy
Website	http://www.cardinalhealth.com
510(k) history	2 submissions · 2 cleared · 2021-2022

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