

K182255 CanGaroo Neuro Envelope (small)Nov 15, 2018
87 days to decisionK182255 · Product code: **FTM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Aug 20, 2018
Decision date	Nov 15, 2018
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	CanGaroo Neuro Envelope (medium) ; CanGaroo Neuro Envelope (large) ; CanGaroo Neuro Envelope (extra large)

APPLICANT

Company	Aziyo Biologics, Inc.
Location	Roswell, GA, US
Contact	Wendy Perreault
510(k) history	4 submissions · 4 cleared · 2017-2020

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