

**K201313 CanGaroo Envelope (small), CanGaroo Envelope (medium), CanGaroo Envelope (large), CanGaroo Envelope (extra large), CanGaroo Envelope (extra extra large) (SubQ)**Jun 15, 2020  
28 days to decisionK201313 · Product code: **FTM** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k201313/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical (FTM)
Date received	May 18, 2020
Decision date	Jun 15, 2020
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201313/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026