

**K161658 Anexa Wound Flush, Sterile Water & Sterile Normal Saline**Sep 14, 2016  
90 days to decisionK161658 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k161658/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Jun 16, 2016
Decision date	Sep 14, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anexa Biomedical, Inc.</b>
Location	Zephyrhills, FL, US
Contact	LENNY BUDLOO
510(k) history	2 submissions · 2 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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