

K172486 Anexa Wound Flush, USP Sterile Water, and USP Sterile Normal Saline (0.9% sodium chloride) 120 mL cup, USP Sterile Water, and USP Sterile Normal Saline (0.9% sodium chloride) 100mL bottle, USP Sterile Water, and USP Sterile Normal Saline (0.9% sodium chloride) 250mL bottle, USP Sterile Water, and USP Sterile Normal Saline (0.9% sodium chloride) 500mL bottleSep 21, 2017
35 days to decisionK172486 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Aug 17, 2017
Decision date	Sep 21, 2017
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Anexa Biomedical, Inc.
Location	Zephyrhills, FL, US
Contact	Lenny Budloo
510(k) history	2 submissions · 2 cleared · 2016-2017

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