

**K172338 Catasyn Advanced Technology Wound Hydrogel**Feb 21, 2018  
203 days to decisionK172338 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172338/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Aug 2, 2017
Decision date	Feb 21, 2018
Days to decision	203 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synedgen, Inc.</b>
Location	Claremont, CA, US
Contact	Shenda Baker
510(k) history	3 submissions · 3 cleared · 2015-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172338/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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