

**K193336 Synvaza Mouth Sore and Wound Rinse, Synvaza II
Mouth Sore and Wound Rinse**May 27, 2020
177 days to decisionK193336 · Product code: **OLR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193336/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Wound Dressing (OLR)
Date received	Dec 2, 2019
Decision date	May 27, 2020
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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