

K181134 G•U•M HYDRAL Dry Mouth Oral Gel, G•U•M HYDRAL Dry Mouth Oral Rinse, G•U•M HYDRAL Dry Mouth Oral SprayJul 13, 2018
74 days to decisionK181134 · Product code: LFD · Dental
Source: <https://www.510kdatabase.net/k181134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saliva, Artificial (LFD)
Date received	Apr 30, 2018
Decision date	Jul 13, 2018
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sunstar Americas, Inc.
Location	Lake Bluff, IL, US
Contact	Liz Bastian
510(k) history	3 submissions · 3 cleared · 2011-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181134/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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