

K211851 Ora-AidJan 11, 2022
210 days to decisionK211851 · Product code: **OLR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Wound Dressing (OLR)
Date received	Jun 15, 2021
Decision date	Jan 11, 2022
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tbm Corporation
Location	Gwangju, KR
Contact	Jaewoong Jung
510(k) history	2 submissions · 2 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	Milly Milly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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