

K183436 OraCureSep 18, 2019
281 days to decisionK183436 · Product code: **OLR** · Dental
Source: <https://www.510kdatabase.net/k183436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Wound Dressing (OLR)
Date received	Dec 11, 2018
Decision date	Sep 18, 2019
Days to decision	281 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	KMC, Inc.
Contact	Ryan Hwang

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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