

K183121 GraypenJul 18, 2019
251 days to decisionK183121 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k183121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Nov 9, 2018
Decision date	Jul 18, 2019
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	AIOBIO Co., Ltd.
Location	Seongnam-Si, KR
Contact	Jongcheol Yoon
510(k) history	2 submissions · 2 cleared · 2019-2024

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