

K213749 G7, Dental Operative Unit and AccessoriesApr 3, 2023
489 days to decisionK213749 · Product code: **EIA** · Dental
Source: <https://www.510kdatabase.net/k213749/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Nov 30, 2021
Decision date	Apr 3, 2023
Days to decision	489 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shinhung Company, Ltd.
Location	Seoul, KR
Contact	Sam Su Kyong
510(k) history	2 submissions · 2 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

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

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