

K221668 Dental Impression MaterialAug 8, 2022
61 days to decisionK221668 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k221668/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jun 8, 2022
Decision date	Aug 8, 2022
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chemoment Materials Co.,Ltd
Location	Hefei, CN
Contact	Mabel Lu
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

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

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