

K211489 Dental Impression MaterialJul 28, 2021
76 days to decisionK211489 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k211489/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	May 13, 2021
Decision date	Jul 28, 2021
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanchang Dental Bright Technology Co., Ltd.
Location	Nanchang, CN
Contact	Justin Qin
510(k) history	1 submissions · 1 cleared · 2021-2021

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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