

K201483 Impression MaterialOct 8, 2020
126 days to decisionK201483 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k201483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jun 4, 2020
Decision date	Oct 8, 2020
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhengzhou Huaer Electro Optics Technology Co., Ltd.
Location	Zhengzhou, CN
Contact	Li XiaoJun
510(k) history	1 submissions · 1 cleared · 2020-2020

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201483/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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