

K201684 A-Silicone for Bite RegistrationSep 24, 2020
94 days to decisionK201684 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k201684/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jun 22, 2020
Decision date	Sep 24, 2020
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Huge Dental Material Corporation
Location	Rizhao City, CN
Contact	Maggie Zheng
510(k) history	8 submissions · 8 cleared · 2016-2026

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