

K192535 Unshaded Dental Zirconia and Pre-Shaded Dental ZirconiaJan 31, 2020
137 days to decisionK192535 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k192535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Sep 16, 2019
Decision date	Jan 31, 2020
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qinhuangdao Audental Metal Technology Co., Ltd.
Location	Qinhuangdao, CN
Contact	Wang Xi
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Beijing Believe-Med Technology Service Co., Ltd.
Contact	Ray Wang

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

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