

K212765 Bloomden Dental Zirconia Blank & Dental Zirconia Pre-Shaded BlankNov 15, 2021
76 days to decisionK212765 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k212765/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Aug 31, 2021
Decision date	Nov 15, 2021
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bloomden Bioceramics (Hunan) Co., Ltd.
Location	Changsha, CN
Contact	Shengyong Liao
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Grace Liu

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

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