

K191221 Cybird LED Curing LightJan 10, 2020
248 days to decisionK191221 · Product code: **EBZ** · Dental
Source: <https://www.510kdatabase.net/k191221/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Activator, Ultraviolet, For Polymerization (EBZ)
Date received	May 7, 2019
Decision date	Jan 10, 2020
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dxm Co., Ltd.
Location	Great Neck, NY, US
Contact	Seung Hyun Kim
510(k) history	6 submissions · 6 cleared · 2004-2020

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

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/k191221/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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