

K213947 Ultrasonic Endo Activation Device (Model:Actor I pro)Sep 8, 2022
265 days to decisionK213947 · Product code: **ELC** · Dental
Source: <https://www.510kdatabase.net/k213947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Dec 17, 2021
Decision date	Sep 8, 2022
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Bomedent Medical Technology Co.,Ltd
Location	Changzhou, CN
Contact	Yang Chunyuan
510(k) history	3 submissions · 3 cleared · 2020-2022

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