

K211358 Implanter incl. AccessoriesNov 21, 2022
567 days to decisionK211358 · Product code: **EBW** · Dental
Source: <https://www.510kdatabase.net/k211358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Foot, Handpiece And Cord (EBW)
Date received	May 3, 2021
Decision date	Nov 21, 2022
Days to decision	567 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guilin Woodpecker Medical Instrument Co., Ltd.
Location	Flintville, TN, US
Contact	Yang Yunfeng
510(k) history	14 submissions · 14 cleared · 2006-2025

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Fu Ailing

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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