

**K211531 Cordless Prophy System, Model: i-Polish**Dec 17, 2021  
214 days to decisionK211531 · Product code: **EKX** · Dental  
Source: <https://www.510kdatabase.net/k211531/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Handpiece, Direct Drive, Ac-powered (EKX) |
| Date received         | May 17, 2021                              |
| Decision date         | Dec 17, 2021                              |
| Days to decision      | 214 days                                  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Guilin Woodpecker Medical Instrument Co., Ltd.</b> |
| Location       | Flintville, TN, US                                    |
| Contact        | Ning Jiakang  |
| 510(k) history | 14 submissions · 14 cleared · 2006-2025               |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Shenzhen Joyantech Consulting Co., Ltd.</b> |
| Contact         | Yoyo Chen                                      |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211531/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 25, 2026