

**K170261 Premium Plus Proply Air Motor**Oct 19, 2017  
265 days to decisionK170261 · Product code: **EFB** · DentalSource: <https://www.510kdatabase.net/k170261/>**SUBMISSION DETAILS**

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|                       |                                      |
|-----------------------|--------------------------------------|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Abbreviated                          |
| Device classification | Handpiece, Air-powered, Dental (EFB) |
| Date received         | Jan 27, 2017                         |
| Decision date         | Oct 19, 2017                         |
| Days to decision      | 265 days                             |
| Third-party review    | No                                   |
| Summary / Statement   | Summary                              |

**APPLICANT**

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|----------------|---|
| Company        | <b>Premium Plus International Limited</b> |
| Location       | Hong Kong, CN                             |
| Contact        | JESSICA MAO                               |
| 510(k) history | 4 submissions · 4 cleared · 2010-2017     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170261/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 31, 2026