

**K211721 PS System**Dec 2, 2021  
181 days to decisionK211721 · Product code: **NYL** · Dental  
Source: <https://www.510kdatabase.net/k211721/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Air-powered, Root Canal Irrigation (NYL)
Date received	Jun 4, 2021
Decision date	Dec 2, 2021
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inter-Med, Inc.</b>
Location	Racine, WI, US
Contact	Brett Arand
510(k) history	8 submissions · 8 cleared · 2009-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211721/> 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 25, 2026