

**K183695 OrthoAnalysis Software**Sep 12, 2019  
255 days to decisionK183695 · Product code: **PNN** · Dental  
Source: <https://www.510kdatabase.net/k183695/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthodontic Software (PNN)
Date received	Dec 31, 2018
Decision date	Sep 12, 2019
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Inteware Co., Ltd.</b>
Location	Minxiong Township, Chiayi Country, CN
Contact	Wayne Tsai
510(k) history	2 submissions · 2 cleared · 2018-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183695/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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