

**K201800 Portable Dental X-ray (NR-F350, CS 2400P, CS 2300P, R2 Port-X)**Dec 28, 2020  
181 days to decisionK201800 · Product code: **EHD** · Radiology  
Source: <https://www.510kdatabase.net/k201800/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, X-ray, Extraoral With Timer (EHD)
Date received	Jun 30, 2020
Decision date	Dec 28, 2020
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>Nanoray Co., Ltd.</b>
Location	Daegu, KR
Contact	Won Hyun Sung
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Wise Company, Inc.</b>
Contact	Sanglok Lee

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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