

**K231181 bright CT**Dec 14, 2023  
232 days to decisionK231181 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k231181/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Apr 26, 2023
Decision date	Dec 14, 2023
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentium Co., Ltd (Ict Branch)</b>
Location	Suwon-Si, KR
Contact	Sang Woo Lee
510(k) history	4 submissions · 4 cleared · 2020-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtechgroup</b>
Contact	Dave Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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