

K190856 SeeFactorCT3Sep 20, 2019
171 days to decisionK190856 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k190856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Apr 2, 2019
Decision date	Sep 20, 2019
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Epica International, Inc.
Location	San Clemente, CA, US
Contact	Daniel Naimey
510(k) history	2 submissions · 2 cleared · 2019-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190856/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026