

K152779 Avex CX2Nov 25, 2015
61 days to decisionK152779 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k152779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Sep 25, 2015
Decision date	Nov 25, 2015
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Opal Orthodontics by Ultradent Products
Location	South Jordan, UT, US
Contact	Marie Hess
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152779/> 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 June 3, 2026