

K111431 B1P ADHESIVEAug 1, 2011
70 days to decisionK111431 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k111431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agent, Tooth Bonding, Resin (KLE)
Date received	May 23, 2011
Decision date	Aug 1, 2011
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pentron Clinical
Location	Orange, CA, US
Contact	Wendy Garman
510(k) history	4 submissions · 4 cleared · 2011-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111431/> 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 8, 2026