

**K973539 ROEKO CALCIUM HYDROXIDE POINTS**Oct 30, 1997  
42 days to decisionK973539 · Product code: **EJK** · DentalSource: <https://www.510kdatabase.net/k973539/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Liner, Cavity, Calcium Hydroxide (EJK)
Date received	Sep 18, 1997
Decision date	Oct 30, 1997
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roeko USA, Inc.</b>
Location	Concord, MA, US
Contact	JAMES DELANEY
510(k) history	1 submissions · 1 cleared · 1997-1997

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