

K952363 OPUS PACEMAKERS (MODELS 4021, 4033, AND 4034)Aug 15, 1995
106 days to decisionK952363 · Product code: **ELA** · Dental
Source: <https://www.510kdatabase.net/k952363/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Hand, Calculus Removal (ELA)
Date received	May 1, 1995
Decision date	Aug 15, 1995
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ela Medical, Inc.
Location	Mchenry, IL, US
Contact	CAHTERINE GOBLE
510(k) history	43 submissions · 36 cleared · 1979-2004

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