

K101054 ROMIAPEX MODEL A-15Sep 3, 2010
141 days to decisionK101054 · Product code: **LQY** · Dental
Source: <https://www.510kdatabase.net/k101054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Locator, Root Apex (LQY)
Date received	Apr 15, 2010
Decision date	Sep 3, 2010
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Romidan, Ltd.
Location	Kiryat-Ono, IL
Contact	EITAN MARGALIT
510(k) history	1 submissions · 1 cleared · 2010-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101054/> 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 20, 2026