

**K071190 ROOT ZX II**Aug 17, 2007  
109 days to decisionK071190 · Product code: **EKX** · Dental  
Source: <https://www.510kdatabase.net/k071190/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Handpiece, Direct Drive, Ac-powered (EKX)
Date received	Apr 30, 2007
Decision date	Aug 17, 2007
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>J. Morita USA, Inc.</b>
Location	Irvine, CA, US
Contact	ROBERT A SILVERMAN
510(k) history	52 submissions · 52 cleared · 1988-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k071190/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 27, 2026