

K141504 T-8000 THEROZONE UNITFeb 24, 2015
263 days to decisionK141504 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k141504/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Jun 6, 2014
Decision date	Feb 24, 2015
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Therozone USA, Inc.
Location	Santa Monica, CA, US
Contact	Rebecca K Pine
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141504/> 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 5, 2026