

K132230 ICE ZIRKON TRANSLUZENTNov 5, 2014
475 days to decisionK132230 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k132230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Jul 18, 2013
Decision date	Nov 5, 2014
Days to decision	475 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zirkonzahn Srl
Location	Silver Creek, NY, US
Contact	DONNA M HARTNETT
510(k) history	8 submissions · 8 cleared · 2014-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132230/> 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 May 26, 2026