

K123545 INCORIS TZIFeb 1, 2013
74 days to decisionK123545 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k123545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powder, Porcelain (EIH)
Date received	Nov 19, 2012
Decision date	Feb 1, 2013
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sirona Dental Systems GmbH
Location	N. Attleboro, MA, US
Contact	FRITZ KOLLE
510(k) history	42 submissions · 42 cleared · 1998-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123545/> 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 16, 2026