

K100290 ESTEMP NEFeb 17, 2010
15 days to decisionK100290 · Product code: **EMA** · Dental
Source: <https://www.510kdatabase.net/k100290/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Dental (EMA)
Date received	Feb 2, 2010
Decision date	Feb 17, 2010
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Spident Co., Ltd.
Location	Incheon, KR
Contact	I.S. HWANG
510(k) history	17 submissions · 17 cleared · 2009-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100290/> 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