

K180365 PRAMA White Implant SystemsJul 8, 2019
511 days to decisionK180365 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k180365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Feb 12, 2018
Decision date	Jul 8, 2019
Days to decision	511 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sweden & Martina S.P.A.
Location	Due Carrare, IT
Contact	Alessia Pezzato
510(k) history	8 submissions · 8 cleared · 2015-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180365/> 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 27, 2026