

**K172560 PREMIUM ONE Implant Systems**Dec 21, 2017  
118 days to decisionK172560 · Product code: **DZE** · Dental  
Source: <https://www.510kdatabase.net/k172560/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Aug 25, 2017
Decision date	Dec 21, 2017
Days to decision	118 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172560/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026