

K190718 Zygomatic ImplantsJul 11, 2019
113 days to decisionK190718 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k190718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Mar 20, 2019
Decision date	Jul 11, 2019
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jjgc Industria E Comercio DE Materiais Dentarios S.A.
Location	Curitiba, BR
Contact	Mariana Soares Hartmann
510(k) history	28 submissions · 28 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	Straumann USA, LLC
Contact	Jennifer M. Jackson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190718/> 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 June 28, 2026