

K222847 Ceramic Brackets OrthometricMay 4, 2023
225 days to decisionK222847 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k222847/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Sep 21, 2022
Decision date	May 4, 2023
Days to decision	225 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthometric - Industria E Comercio DE Produtos Medicos
Location	Marilia, BR
Contact	Silvio Zilio
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Pr Servicios Regulatorios Administrativos Ltda
Contact	Tatiana Jabor Botura

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/k222847/> 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