

K212729 Bone Cement-Normal ViscosityMay 31, 2022
277 days to decisionK212729 · Product code: **LOD** · Orthopedic
Source: <https://www.510kdatabase.net/k212729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement (LOD)
Date received	Aug 27, 2021
Decision date	May 31, 2022
Days to decision	277 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomechanica Industria E Comercio de Produtos Ortopedicos Ltda
Location	Jau, BR
Contact	Thais Busquim
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Passarini Regulatory Affairs/ PR Servicos
Contact	Graziela Brum

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/k212729/> 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