

K192682 Orthocem, Ortho BiteAug 14, 2020
323 days to decisionK192682 · Product code: **DYH** · Dental
Source: <https://www.510kdatabase.net/k192682/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Sep 26, 2019
Decision date	Aug 14, 2020
Days to decision	323 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentscare Ltda
Location	Joinville, BR
Contact	Roberta Uyara
510(k) history	10 submissions · 10 cleared · 2019-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192682/> 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 25, 2026