

K213742 Infinity Pro, Logic, Quality, SprintOct 19, 2022
324 days to decisionK213742 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k213742/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Nov 29, 2021
Decision date	Oct 19, 2022
Days to decision	324 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Olsen Indústria e Comércio S.A.
Location	Palhoça, BR
Contact	Ana Cláudia Espíndola
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Techlink International
Contact	Lilian Llull

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213742/> 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