

K180935 Infinity / Infinity Cross Flex Dental SystemsFeb 5, 2020
666 days to decisionK180935 · Product code: **EIA** · Dental
Source: <https://www.510kdatabase.net/k180935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Apr 10, 2018
Decision date	Feb 5, 2020
Days to decision	666 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Olsen Industria E Comercio S.A.
Location	Palho?a -, BR
Contact	Ana Claudia Espindola
510(k) history	1 submissions · 1 cleared · 2020-2020

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/k180935/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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