

K223338 Toothsi, SmilealignersFeb 9, 2023
100 days to decisionK223338 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k223338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Nov 1, 2022
Decision date	Feb 9, 2023
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Makeo Healthcare Technologies Private Limited
Location	Mumbai, IN
Contact	Manjul Jain
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Intrust
Contact	Sanjeev Kumar Gupta

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/k223338/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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