

K222054 Denti.AI Auto-ChartNov 22, 2022
133 days to decisionK222054 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k222054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 12, 2022
Decision date	Nov 22, 2022
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Denti.AI Technology, Inc.
Location	Toronto, CA
Contact	Lyudmila Tuzova
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting
Contact	Donna-Bea Tillman

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

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