FDA 510(k) Premarket Notification

K230144 Denti.AI Detect

CLEARED

Oct 6, 2023
261 days to decision

K230144 · Product code: **MYN** · Radiology
Source: https://www.510kdatabase.net/k230144/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Medical Image (MYN)
Date received	Jan 18, 2023
Decision date	Oct 6, 2023
Days to decision	261 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