FDA 510(k) Premarket Notification

K222666 X-View 3D Pan/X-View 2D Pan

CLEARED

Jul 10, 2023
307 days to decision

K222666 · Product code: **OAS** · Radiology
Source: https://www.510kdatabase.net/k222666/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Sep 6, 2022
Decision date	Jul 10, 2023
Days to decision	307 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Trident S.R.L**
Location	Assago, IT
Contact	Giorgio Rizzo
510(k) history	5 submissions · 5 cleared · 2016-2023

REGULATORY CONSULTANT

Consulting firm	**The 510k Consulting, LLC**
Contact	Joyce St. Germain

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222666/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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