FDA 510(k) Premarket Notification

K212175 DynaCAD

CLEARED

Aug 2, 2021
21 days to decision

K212175 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k212175/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 12, 2021
Decision date	Aug 2, 2021
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Invivo Corporation**
Location	Pewaukee, WI, US
Contact	Liselotte Kornmann
510(k) history	29 submissions · 29 cleared · 2005-2021

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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