FDA 510(k) Premarket Notification

K210241 ImplaStation

CLEARED

Dec 3, 2021
308 days to decision

K210241 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k210241/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 29, 2021
Decision date	Dec 3, 2021
Days to decision	308 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Prodigident, Inc.**
Location	Roselle, IL, US
Contact	Andrii Gromov
510(k) history	1 submissions · 1 cleared · 2021-2021