FDA 510(k) Premarket Notification

K212321 JiveX (Model Number / Release: 5.3)

CLEARED

Sep 23, 2021
59 days to decision

K212321 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k212321/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 26, 2021
Decision date	Sep 23, 2021
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Visus Health IT GmbH**
Location	Bochum, DE
Contact	Axel Schreiber
510(k) history	4 submissions · 4 cleared · 2018-2023