FDA 510(k) Premarket Notification

K202369 RXS 1000

CLEARED

Sep 15, 2021
392 days to decision

K202369 · Product code: **MUH** · Radiology
Source: https://www.510kdatabase.net/k202369/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Aug 19, 2020
Decision date	Sep 15, 2021
Days to decision	392 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Rolence Enterprise, Inc.**
Location	Taoyuan, TW
Contact	Ben Chang
510(k) history	2 submissions · 2 cleared · 2018-2021