

K202369 RXS 1000Sep 15, 2021
392 days to decisionK202369 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202369/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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