FDA 510(k) Premarket Notification

K213128 IntraOp VSP Software Device

CLEARED

Oct 21, 2022
389 days to decision

K213128 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k213128/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 27, 2021
Decision date	Oct 21, 2022
Days to decision	389 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Xironetic, LLC**
Location	Oklahoma City, OK, US
Contact	Christian El Amm
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Paladin Medical, Inc.**
Contact	Elaine Duncan

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