FDA 510(k) Premarket Notification

K230012 Atomica Planner

CLEARED

Feb 2, 2023
30 days to decision

K230012 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k230012/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 3, 2023
Decision date	Feb 2, 2023
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Atomica Technology, Inc.**
Location	Atlanta, GA, US
Contact	Yahia Megahed
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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