FDA 510(k) Premarket Notification

K252195 ARTICOR planner

CLEARED

Mar 27, 2026
256 days to decision

K252195 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k252195/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 14, 2025
Decision date	Mar 27, 2026
Days to decision	256 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Artiness S.R.L**
Location	Milan, IT
Contact	Monica R. Montanez
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Namsa**
Contact	Monica R. Montanez

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