FDA 510(k) Premarket Notification

K202822 Helianthus

CLEARED

Dec 15, 2021
447 days to decision

K202822 · Product code: **MUE** · Radiology
Source: https://www.510kdatabase.net/k202822/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full Field Digital, System, X-ray, Mammographic (MUE)
Date received	Sep 24, 2020
Decision date	Dec 15, 2021
Days to decision	447 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Metaltronica Spa**
Location	Pomezia Rm, IT
Contact	Gloria Pesce Delfino
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Emergo Europe Consulting**
Contact	Rachel Paul

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