FDA 510(k) Premarket Notification

K222112 Comfort Marker 2.0

CLEARED

Mar 30, 2023
255 days to decision

K222112 · Product code: **QRN** · Radiology
Source: https://www.510kdatabase.net/k222112/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiation Therapy Marking Device (QRN)
Date received	Jul 18, 2022
Decision date	Mar 30, 2023
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medical Precision BV**
Location	Zwolle, NL
Contact	Blerta Kukaj
510(k) history	2 submissions · 1 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	**Msquared Associates, Inc.**
Contact	Cherita Jones

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

CLINICAL EVIDENCE - NCT05371795

Comparison on Radiotherapy Permanent Skin Marking With Lancets and an Electric Marking Device

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	100 patients (actual)
Study sites	1 site
Condition studied	Radiotherapy; Tattooing
Primary purpose	Other
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Sep 1, 2022
Sponsor	Instituto Portugues de Oncologia, Francisco Gentil, Porto (Other)

Primary outcome

Patients' comfort

Secondary outcome

RTTs' satisfaction

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05371795