FDA 510(k) Premarket Notification

CLEARED

K223855 FEops HEARTguideTM, FEops HEARTguideTM ALPACA

Jun 6, 2023
165 days to decision

K223855 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k223855/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 23, 2022
Decision date	Jun 6, 2023
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Feops NV**
Location	Gent-Zwijnaarde, BE
Contact	Peter Mortier
510(k) history	4 submissions · 3 cleared · 2021-2025