FDA 510(k) Premarket Notification

K214066 FEops HEARTguide

CLEARED

Feb 25, 2022
60 days to decision

K214066 · Product code: **QQI** · Cardiovascular
Source: https://www.510kdatabase.net/k214066/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Cardiovascular Implant Simulation Software Device (QQI)
Date received	Dec 27, 2021
Decision date	Feb 25, 2022
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Orthogrow NV**
Contact	Niels Festjens

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